THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. **a Massachusetts Corporation** **Plaintiff,** **v.** **Arthrex, Inc.** **a Delaware Corporation and** **Pearsalls Ltd.** **a Private Limited Company** **of the United Kingdom** **Defendants.**	)	**Civil No. 04-12457 PBS**

Mitek's Motion to Strike Dr. Mukherjee's Declarations and Exhibits

Table of Contents

Table of Authorities

Federal Cases

Federal Statutes

On September 15, 2006, in its reply to its motions for summary judgment of no infringement and claims construction, Arthrex submitted a declaration from Dr. Mukherjee. But Dr. Mukherjee's declaration contains new expert opinions and new exhibits that were not previously produced during expert discovery, which closed at the end of July 2006. It is fundamentally unfair for Arthrex to submit new expert opinions, based on new exhibits, on *reply* that Mitek and its experts did not have the opportunity to consider during expert discovery, much less respond to during the *Markman* and Summary Judgment proceedings. Further, Arthrex's tactic of holding these opinions until reply enabled Dr. Mukherjee to evade being cross-examined on these opinions. As Dr. Mukherjee's new opinions violate this Court's scheduling order, FED. R. CIV. P. 26(a)(2)(B), and the fundamental notion of fairness, they should be stricken.

Also on September 15, 2006, Arthrex submitted another declaration from Dr. Mukherjee in response to Mitek's motion to strike the Allied Signal brochure. Again, this declaration contains new expert opinions. Dr. Mukherjee did not consider the Allied Signal brochure in forming his expert opinions, and he should not be permitted to provide new opinions about it now. Thus, Mitek likewise moves to strike this declaration.

I. Dr. Mukherjee Submitted New Opinions Based On New Exhibits On Reply to its Markman and Summary Judgment Motions

Except for some previous noticed depositions, fact discovery closed on February 1, 2006. The parties conducted expert discovery between March and July 2006. Dr. Mukherjee submitted three expert reports between March and April 2006 (Ex. 1). Dr. Mukherjee was deposed on June 13 to 14, 2006 (Ex. 2).

After expert discovery closed at the end of July, the parties served opening dispositive motions and *Markman* briefs on August 11, 2006. The parties served opposition briefs on

September 1, 2006, and reply briefs on September 15, 2006. On September 1, 2006, Mitek moved to strike the Allied Signal Brochure, which Arthrex relied upon in its opening briefs. Arthrex opposed Mitek's motion to strike on September 15, 2006.

On September 15, 2006, in support of its reply briefs to its *Markman* and summary judgment motions, Arthrex submitted Dr. Mukherjee's declaration ("Markman/Summary Judgment Declaration") (Ex. 3). In his Markman/Summary Judgment Declaration, Dr. Mukherjee provided new opinions regarding the relative tensile strength and stiffness of UHMWPE and so-called general purpose PE fibers that he had not expressed in any of his three previous reports (id. at ¶¶3-8 and 12). Further, Dr. Mukherjee relied on new exhibits that he had not considered in any of his three previous reports and had not mentioned during his deposition (*id*. at Exhibits B-D). Arthrex did not produce these exhibits during fact discovery, even though they are directly responsive to Mitek document requests from early 2005 (Ex. 4 at Requests Nos. 4, 8, 11, 22, 23, 49, and 52). Further, Dr. Mukherjee did not produce the new exhibits in response to a subpoena for documents during expert discovery (Ex. 5).

As Arthrex and Dr. Mukherjee failed to produce these opinions and exhibits during expert discovery, or even before reply briefs were filed, Mitek's experts did not have a chance to consider them. Further, as the documents were not produced during fact discovery, Mitek did not have the opportunity to investigate them. Also, Mitek was deprived of the opportunity to cross-examine Dr. Mukherjee about these opinions and exhibits.

In support of Arthrex's opposition to Mitek's motion to strike the Allied Signal brochure, Arthrex submitted another declaration by Dr. Mukherjee (Ex. 6). In his declaration, Dr. Mukherjee opined regarding the Allied Signal Brochure. But in his three previous reports, he had not considered the Allied Signal brochure, and he did not mention it at his deposition. The

Allied Signal brochure first appeared during expert discovery at Dr. Hermes' deposition on July 25, 2006, just two days before expert discovery closed. The Allied Signal brochure was one of about 95,000 pages of documents produced by Mitek in this case.

II. Dr. Mukherjee's Summary Judgment/Markman Declaration ¶¶3-8, 12 and 13 and Exhibits B-E and His Allied Signal Declaration Should Be Stricken

A. Dr. Mukherjee's Summary Judgment/Markman Declaration Exhibits B-E and ¶¶3-8, 12 and 13 Should Be Stricken For Failing to Comply with FED. R. CIV. P. 26(a)(2)(B) and This Court's Scheduling Order

FED. R. CIV. P. 26(a)(2)(B) clearly required Dr. Mukherjee's expert reports to have a "complete statement of all opinions to be expressed and the basis and reasons therefore; and the data or other information considered by the witness in forming the opinions." But Dr. Mukherjee did not comply with this rule. Rather, Dr. Mukherjee has now submitted new opinions in ¶¶3-8, 12 and 13 of his declaration and has now relied on new information, namely declaration exhibits B-E. Having failed to comply with FED. R. CIV. P. 26(a)(2)(B), Dr. Mukherjee's new opinion in declaration ¶¶3-8, 12 and 13, and new exhibits B-E should be stricken.

Dr. Mukherjee submitted three expert reports between March and April 2006. Not only did he not rely on Declaration Exhibits B-E, but he did not even identify them among his documents considered (Ex. 1). Dr. Mukherjee was deposed on June 13 to 14, 2006 and did not mention any of the five documents. Dr. Mukherjee admitted at his deposition that his three reports listed all of the materials that he had considered (Ex. 7 at 134:8-24). Expert discovery closed, and Dr. Mukherjee made no mention of relying on any of the four exhibits.

Dr. Mukherjee's declaration exhibits B-E should also be stricken because not only were Exhibits B-E not identified by Dr. Mukherjee, they were not identified or produced by Arthrex during fact discovery. Arthrex is clearly trying to rely on these documents, but at no time prior

to submitting the documents with reply briefing did Arthrex produce them as part of its disclosure obligations under FED. R. CIV. P. 26(a)(1)(B). Declaration exhibits B-D were clearly responsive to Mitek Document Requests Nos. 4, 11, 22, 23, 49, and 52 because Arthrex is attempting to use them as a basis for Dr. Mukherjee's new claim construction and infringement opinions. Further, Declaration Exhibit E was responsive to Document Requests Nos. 4, 8, 49, and 52, as Arthrex is attempting to use it as a basis for Dr. Mukherjee's opinion on validity issues and sterilization with respect to the 575 Patent. Having failed to produce the documents during discovery, Arthrex deprived Mitek of the opportunity to take discovery regarding them.

Dr. Mukherjee's opinions as set forth in ¶¶3-8, 12 and 13 of his declaration are new opinions that were not previously expressed in any of his three prior reports. Dr. Mukherjee did not discuss the specific relative stiffness of UHMWPE fibers and "general purpose polyethylene fibers" in his prior reports. Further, nowhere in his prior reports did he quantify any amount of difference in "stiffness," fiber tensile modulii or specific values for the modulii, relative strengths of fibers, fiber tensile strength values, the strength of UHMWPE fibers relative other fibers, or the molecular weight ranges of UHMWPE relative to "general purpose PE," as set forth in these paragraphs.

At his deposition, Dr. Mukherjee testified that his three expert reports contained all of his opinions, and he had no opinions that were not contained in his reports:

Q. Okay. Now, you have three reports, right?
A. Yeah.

Q. So, they list all of the -- they list and describe all of the opinions that you have in this case?
A. That's correct.
Q. Okay. Do you have any opinions that you've formed subsequent to signing these reports with respect to this case?

THE WITNESS: No.
BY MR. BONELLA:
Q. Okay. Have you looked at any additional materials since you signed the last report, Exhibit 356?
THE WITNESS: Related to this case?
BY MR. BONELLA:
Q. Yes.
A. Okay. No.
Q. Are you or have you been asked to prepare another expert report in this case?
A. No.

(Ex. 7 at 134:25-135:22) (objection omitted). Having failed to comply with FED. R. CIV. P. 26(a)(2)(B) and this Court's scheduling order, Dr. Mukherjee should not be permitted to submit new information well after expert discovery has closed.

B. Dr. Mukherjee's Allied Signal Declaration Submitted With Arthrex's Motion to Strike Should Be Stricken For Failing to Comply with FED. R. CIV. P. 26(a)(2)(B) and This Court's Scheduling Order

Arthrex and Dr. Mukherjee likewise violated FED. R. CIV. P. 26(a)(2)(B)'s disclosure requirements and this Court's scheduling order by providing new opinions based on new exhibits in Dr. Mukherjee's Allied Signal Declaration.

Dr. Mukherjee did not consider the Allied Signal brochure in any of his three expert reports (Ex. 1). Nor did he produced it in response to a subpoena for documents (Ex. 5). Dr. Mukherjee did not mention the Allied Signal brochure at his deposition, and he admitted at his deposition that his reports listed all of the materials that he considered (Ex. 7 at 134:8-24). Expert discovery closed, and Dr. Mukherjee made no mention of having relied on the Allied Signal brochure. Having failed to provide his opinions regarding the Allied Signal brochure during expert discovery, he has violated this Court's scheduling order and FED. R. CIV. P. 26(a)(2)(B). Thus, Dr. Mukherjee's Allied Signal Declaration should be stricken.

C. Dr. Mukherjee's Untimely Opinions And Exhibits Should Be Stricken Because Admitting Them Would Severely Prejudice Mitek

Permitting Dr. Mukherjee to basically file new expert reports well *after the close of expert discovery* and *on reply* to summary judgment motions would severely prejudice Mitek. Mitek and its experts were not afforded the opportunity to consider Dr. Mukherjee's new opinions based on the these documents during the expert discovery period, research them, and form opinions regarding them. Through Arthrex's tactics, Dr. Mukherjee evaded cross-examination, the litigation procedure for testing the veracity of his new opinions. Further, Arthrex deprived Mitek of the opportunity to take fact discovery on the authenticity of these new exhibits and their contents.

But most importantly, Arthrex submitted information in support of its *Markman* and summary judgment motions that has not been reviewed and considered by Mitek and its experts. From this briefing, this Court will render a *Markman* decision. Arthrex should not be permitted to simply violate the Court's scheduling order and FED. R. CIV. P. 26(a)(2)(B) by submitting expert opinions and information as truth on reply to its motions that was not raised during the litigation at the proper time and vetted. Through its tactics, Arthrex presented expert testimony and evidence on issues, which the Court will now decide, that Mitek did not have the opportunity to rebut. That tactic could not be more prejudicial.

Notably, Mitek is not moving to strike statements in Dr. Mukherjee's Markman/Summary Judgment declaration that are different, but generally in accordance with what he stated in his expert reports. Rather, Mitek is moving to strike the new opinions that rely on new exhibits that were not previously produced. That is what is fundamentally unfair.

D. Although Arthrex May Claim That Dr. Mukherjee's New Opinions Are Justified Because Arthrex is Allegedly Responding to New Issues, That Is Wrong

Mitek expects that Arthrex will seek to justify Dr. Mukherjee's untimely opinions as allegedly responding to new issues raised by Mitek. But that is not true. Since shortly after this case was filed, Arthrex has been alleging that the claimed "PE" does not include UHMWPE. Mitek has argued throughout the case that "PE" includes UHMWPE and, if not, UHMWPE is equivalent to the claimed first fiber-forming materials. Dr. Mukherjee's new opinions are about alleged differences between UHMWPE and what Arthrex calls "general purpose PE." Dr. Mukherjee's noninfringement opinion in his expert reports was based on this distinction. Thus, these are not new issues. Rather, the truth is that Arthrex is trying to use new expert opinions based on new documents to support its arguments.

Arthrex will not be prejudiced by striking Dr. Mukherjee's declarations. Expert discovery lasted for about five months, so Arthrex had ample time to submit its newly-filed information. Dr. Mukherjee presented three expert reports and was deposed for about a day and a half. He had plenty of opportunity to render these opinions and cite whatever information he wanted in his reports. He did not, and there is no excuse for his or Arthrex's delay until Arthrex replied.

E. If Arthrex Alleges That It Is "Supplementing" Dr. Mukherjee's Report, That Should Not Be Permitted Because It Is A Violation Of This Court's Scheduling Order and Certainly Should Not Be Permitted On Reply To Summary Judgment And *Markman* Briefing

FED. R. CIV. P. 26(e)(1) provides a "limited exception" for *supplementing* an expert's report. *Minebea Co., Ltd. v. Papst*, 231 F.R.D. 3, 7 (D. D.C. 2005). In relevant part, FED. R. CIV. P. 26(e)(1) provides that a party may "supplement" an expert report "if the party learns that in some material respect the information disclosed is incomplete or incorrect and if the additional

or corrective information has not otherwise been made known to the other parties during the discovery process or in writing." But FED.R.CIV.P. 26(e)(1) is not a provision for *redoing* expert reports or simply providing new opinions because the expert could have done a better job, as Arthrex apparently believes here.[1] Nor does Rule 26(e)(1) grant a party the right to supplement reports merely because it believes such reports would be "desirable" or "necessary." *Minebea*, 231 F.R.D. at 7 (*citing Keener v. United States*, 181 F.R.D. 639, 640 (D. Mont. 1998)). Rather, the supplementation permitted by Rule 26(e)(1) is generally limited to the "narrow purpose of correcting inaccuracies or adding information that was not available at the time of the initial report." *Id.*; *DAG Enters.*, 226 F.R.D. at 109-110 (holding that "supplementation under the Rules means correcting inaccuracies, or filling the interstices of an incomplete report," not substituting reports).

A factor in denying requests for supplementation is whether there was a reason that the expert could not have provided the opinions during expert discovery.[2] There is absolutely no

---

[1] *DAG Enters., Inc. v. Exxon Mobil Corp.*, 226 F.R.D. 95, 109-10 (D. D.C. 2005) (holding that supplementation does not permit a party to simply substitute an old report for a new one); 6 JAMES WM. MOORE ET AL., MOORE'S FEDERAL PRACTICE ¶ 26.131[2] (3d ed. 2006) (explaining that "[a] party may not use a supplemental report to disclose information that should have been disclosed in the initial report, thereby circumventing the requirement for a timely and complete report") (Ex. 8); *Coles v. Perry*, 217 F.R.D. 1, 3 (D. D.C. 2003) (striking late-filed report styled "supplemental opinion," noting that "Fed. R. Civ. P. 26(e) does not grant a license to supplement a previously filed expert report because a party wants to"); *Akeva L.L.C. v. Mizuno Corp.*, 212 F.R.D. 306, 310 (M.D. N.C. 2002) (holding that Rule 26(e)(1) "does not cover failures of omission because the expert did an inadequate or incomplete preparation"); *Stein v. Foamex Int'l, Inc.*, No. 00-2356, 2001 U.S. Dist. LEXIS 12211, at *15 (E.D. Pa. Aug. 15, 2001) (Ex. 9) (holding that a late filed affidavit was not a supplemental expert report because it does not contradict the original report in any material respect); *Keener*, 181 F.R.D. at 640 (second expert report was not a supplemental report because it was not shown that the first report was inaccurate or incomplete in some material respect).

[2] *Minebea*, 231 F.R.D. at 7 (citing *Keener*, 181 F.R.D. at 640); *Saint-Gobain Corp. v. Gemtron Corp.*, No. 1:04-cv-387, 2006 U.S. Dist. LEXIS 28263, at *4-5 (W.D. Mich. May 9, 2006) (Ex. 10) (holding that expert could not supplement where party trying to supplement could not show that the new information was unknown to it); *Schweizer v. DEKALB Swine Breeders*,

legitimate reason why Arthrex could not have provided Dr. Mukherjee's newly presented opinions previously. Accordingly, Arthrex should not be permitted to "supplement" Dr. Mukherjee's expert reports now because it is a violation of FED.R.CIV.P. 26(e)(1). Further, it should not be permitted to so on reply to its summary judgment and *Markman* motions.

Mitek's experts and Mitek's counsel spent a significant amount of time analyzing Dr. Mukherjee's three reports. Mitek's technical experts, Dr. Hermes and Dr. Brookstein, each submitted two expert reports. All of the experts were deposed. Mitek should not be burdened with new opinions based on new documents now at this late date.

III. Conclusion

On reply to its Markman and Summary Judgment motions, Arthrex has submitted new opinions from Dr. Mukherjee that are based on new documents that were not produced or considered during fact or expert discovery. That violates all notions of fairness. Accordingly, Mitek moves to strike:

1. Dr. Mukherjee's Declaration ¶¶3-8, 12 and 13 and Declaration Exhibits B-E submitted with Arthrex's Replies to its Summary Judgment/*Markman* motions.

2. All references to Dr. Mukherjee's Declaration ¶¶3-8, 12 and 13 and Declaration Exhibits B-E submitted with Arthrex's Replies to its Summary Judgment/*Markman* motions.

3. Dr. Mukherjee's Declaration submitted with its Opposition to Mitek's Motion to Strike Hearsay Exhibit and All Citation and Commentary Thereto.

Inc. 954 F. Supp. 1495, 1510 (D. Kan. 1997) (excluding supplemental report of expert containing new opinions when there was no reason the opinions could not have been expressed in the expert's original report).

Date: September 22, 2006

/s/ Erich M. Falke
Dianne B. Elderkin
Lynn A. Malinoski
Michael J. Bonella
Erich M. Falke
Woodcock Washburn LLP
One Liberty Place 46th Floor
Philadelphia, PA. 19103
215-568-3100

Daniel J. Gleason (BBO #194900)
Nutter McClennen & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA. 02210-2604

CERTIFICATE OF SERVICE

I certify that I am counsel for DePuy Mitek, Inc. and that true and correct copies of:

Mitek's Motion to Strike Dr. Mukherjee's Declarations and Exhibits

were served on counsel for Defendants Arthrex, Inc. and Pearsalls Ltd. on this date via the Court's e-mail notification with the following recipients being listed as filing users for Defendants:

Charles W. Saber
Dickstein Shapiro
1825 Eye Street, NW
Washington, DC 2006
saberc@dicksteinshapiro.com

Raymond P. Ausrotas
Todd & Weld LLP
28 State Street, 31st Floor
Boston, MA 02109
rausrotas@toddweld.com

Dated: September 22, 2006

/s/ Erich M. Falke
Erich M. Falke

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Exhibit 1

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING INVALIDITY OF U.S. PATENT NO. 5,314,446

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his expert report as follows.

EXHIBIT 1 - DOCUMENTS REVIEWED AND CONSIDERED

1) U.S. Patent No. 5,314,446

2) Prosecution History of U.S. Patent No. 5,314,446

3) U.S. Patent No. 4,610,688

4) U.S. Patent No. 5,120,802

5) U.S. Patent No. 4,563,392

6) U.S. Patent No. 4,543,286

7) U.S. Patent No. 5,318,575

8) U.S. Patent No. 6,716, 234

9) U. S. Patent No. 3,454,011

10) U.S. Patent Application No. 2005/0149118

11) U.S. Patent Application No. 2004/0267313

12) UK Patent Application No. 2,218,312A to Burgess

13) Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture,* Arch Ophthalmol – Vol. 103, December 1985 (ARM 25132 - 137)

14) *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* (PR 08420 – 29)

15) Arthrex's responses to DePuy Mitek's interrogatories

16) DePuy Mitek's responses to Arthrex's interrogatories

17) Dr. Mark Steckel's laboratory notebooks

18) Deposition transcript of Dr. Mark Steckel

19) Deposition transcript of Dennis D. Jamiolkowski

20) Ethicon document DMI 095020

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc.
a Massachusetts Corporation

Plaintiff,

v.

Arthrex, Inc.
a Delaware Corporation

Defendant.

Civil Action No. 04-12457 PBS

RESPONSIVE EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE CONCERNING NON-INFRINGEMENT OF U.S. PATENT NO. 5,314,446 AND OTHER MATTERS

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his responsive expert report concerning non-infringement and other matters as follows.

EXHIBIT 1 - DOCUMENTS REVIEWED AND CONSIDERED

1) U.S. Patent No. 5,314,446

2) Prosecution History of U.S. Patent No. 5,314,446

3) Expert Report of Dr. David Brookstein

4) U.S. Patent No. 4,610,688

5) U.S. Patent No. 5,120,802

6) U.S. Patent No. 5,318,575

7) U.S. Patent No 4,563,392

8) U.S. Patent No. 4,543,286

9) U.S. Patent No. 5,147,383

10) U.S. Patent No. 5,089,013

11) U.S. Patent No. 4,532,929

12) U.S. Patent No. 4,994,074

13) U.S. Patent No. 4,983,180

14) U.S. Patent No. 4,649,920

15) UK Patent Application No. 2,218,312A to Burgess

16) Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture,* Arch Ophthalmol – Vol. 103, December 1985 (ARM 25132 - 137)

17) *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* (PR 08420 – 29)

18) Arthrex's responses to DePuy Mitek's interrogatories

19) DePuy Mitek's responses to Arthrex's interrogatories

20) Dr. Mark Steckel's laboratory notebooks

21) Deposition transcript of Dr. Mark Steckel

22) Deposition transcript of Dennis D. Jamiolkowski

23) Deposition transcript of Donald Grafton

24) Deposition transcript of Robert Sluss

25) Rodeheaver et al., Knotting and Handling Characteristics of Coated Synthetic Absorbable Suture, Journal of Surgical Research 35, 525-530 (1983).

26) Herrman, MD, Tensile Strength and Knot Security of Surgical Suture Materials, The American Surgeon, 209-217 (April 1971).

27) DMI 60231-34

28) DMI 94394

29) Arthrex FiberWire Directions for Use

30) DMI 39421, 39438

31) Ethicon Wound Closure Manual

32) ARM 699

33) Comparative Suture Testing Report of Center for Tribology, Inc.

34) Report of Robert Burks, MD

35) Pearsalls knot strength data document

36) Stiffness data for nylon and PET (www.maropolymeronline.com)

37) FiberStick marketing materials

38) Pearsalls Silkworm documents (PR 8400-03)

39) ARM 10564

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	Civil Action No. 04-12457 PBS

REBUTTAL EXPERT REPORT OF DR. DEBI PRASAD MUKHERJEE

Pursuant to the provisions of Rule 26(a)(2) of the Federal Rules of Civil Procedure, the Joint Case Management Statement adopted by the Court on February 18, 2005, and agreement between the parties, the undersigned, Dr. Debi Prasad Mukherjee, an expert witness for Defendants Arthrex, Inc. and Pearsalls, Limited (together, "Defendants") hereby sets forth his rebuttal expert report as follows.

EXHIBIT 1 - DOCUMENTS REVIEWED AND CONSIDERED

1) U.S. Patent No. 5,314,446

2) Prosecution History of U.S. Patent No. 5,314,446

3) U.S. Patent No. 4,610,688

4) U.S. Patent No. 5,120,802

5) U.S. Patent No. 5,318,575

6) U.S. Patent No. 6,716, 234

7) UK Patent Application No. 2,218,312A to Burgess

8) Cohan, et al., *An Evaluation of Ultrastrong Polyethylene Fiber as an Ophthalmic Suture,* Arch Ophthalmol – Vol. 103, December 1985 (ARM 25132 - 137)

9) *Dyneema SK60, High strength/ high modulus fiber, Properties & Applications* (PR 08420 – 29)

10) Dr. Mark Steckel's laboratory notebooks

11) Deposition transcript of Dr. Mark Steckel

12) Cheng et al., *Radiation Processing for Modification of Polymers,* 2003 Annual Technical Conference of the Society of Plastics Engineering

13) Ethicon document DMI 095020

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Exhibit 2

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

- - - - -

The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

- - - - -

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Civil Action No. 04-12457 PBS

DEPUY MITEK, INC., a Massachusetts Corporation,

Plaintiff,

v.

ARTHREX, INC., a Delaware Corporation

Defendant.

Videotaped Deposition of DEBI PRASAD MUKHERJEE

- VOLUME TWO -

Washington, DC

Wednesday, June 14, 2006

The videotaped deposition of DEBI PRASAD MUKHERJEE, Volume Two, was held on Wednesday, June 14, 2006, commencing at 9:12 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, Northwest, Washington, DC, before Mary Ann Payonk, RDR, Certified Realtime Reporter, Registered Diplomate Reporter and Notary Public.

Exhibit 3

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc., *et al.* a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

DECLARATION OF DR. DEBI PRASAD MUKHERJEE

1. My name is Dr. Debi Prasad Mukherjee. I am an Associate Professor and the Coordinator of Bioengineering in the Department of Orthopaedic Surgery at the Louisiana State University Health Sciences Center, in Shreveport, Louisiana. My CV is attached as Ex. A.

2. I am the same Dr. Debi Prasad Mukherjee who prepared the "Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446" dated March 3, 2006, the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters" dated March 24, 2006, and the "Rebuttal Expert Report of Dr. Debi Prasad Mukherjee" dated April 13, 2006.

3. I have been asked to provide my opinion regarding the relative stiffness and the relative tensile strength of ultra high molecular weight polyethylene (UHMWPE) fiber and general purpose polyethylene fiber.

4. It is my opinion that UHMWPE fiber is greater than approximately 100 times more stiff than the general purpose polyethylene fiber to which it is being compared. That is, the general

purpose polyethylene fiber is greater than approximately 100 times more pliable than UHMWPE fiber.

5. My opinion regarding the relative stiffness of UHMWPE fiber and general purpose polyethylene fiber is based on the fact that UHMWPE fiber has a tensile modulus on the order of 117GPa (Giga-Pascals) (Ex. B at 5-26), whereas general purpose polyethylene fiber has a tensile modulus on the order of 0.849GPa. Ex. C at Figure 12 (HMW HDPE). The higher a fiber's tensile modulus, the more stiff the fiber. Accordingly, the general purpose polyethylene would be considered a pliable substance when used with suture and UHMWPE would be considered a stiff material when applied to suture.

6. It is also my opinion that UHMWPE fiber is greater than approximately 60 times stronger than the general purpose polyethylene fiber. That is, the general purpose polyethylene fiber is greater than approximately 60 times weaker than UHMWPE fiber.

7. My opinion regarding the relative strength of UHMWPE fiber and the general purpose polyethylene fiber is based on the fact that UHMWPE fiber has a tensile strength on the order of 2590MPa (Mega-Pascals) (Ex. B at 5-26), whereas the general purpose polyethylene fiber has a tensile strength on the order of 40MPa. Ex. C at Figure 11 (HMW HDPE).

8. It is my opinion that UHMWPE is one of the strongest synthetic fibers ever created. Ex. B at 5-26.

9. It is also my opinion that general purpose polyethylene has been used in industry for decades and has established itself as a general purpose commodity polymer.

10. Since its introduction in fiber form in the 1980s, UHMWPE, has been considered a specialized high performance product. Ex. B at 5-26.

11. The key structural characteristics – molecular weight and molecular structure – of UHMWPE are very different than that of general purpose PE. Ex. D at 4.

12. UHMWPE has a molecular weight of up to approximately 6 million, whereas general purpose PE has a molecular weight of up to approximately 200,000. Ex. D at 4.

13. UHMWPE also exhibits a much higher degree of crystalline orientation as compared with general purpose PE. These differences in molecular structure are the basis for UHMWPE's superior strength characteristics. Ex. D at 4, 6.

14. It is well known in the surgical suture art that a suture must be sterilized before it can be used in any surgical application.

15. FDA Publication "510K Sterility Review Guidance K90-1; Guidance for Industry and FDA" governs the sterilization of medical devices, including surgical suture. Ex. E.

16. It is my opinion that a person of ordinary skill in the surgical suture art would understand that the suture disclosed in U.S. Patent No. 5,318,575 must be sterilized before it can be used in a surgical application.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed on: Sept 15, 2006

Debi Prasad Mukherjee

Dr. Debi Prasad Mukherjee

EXHIBIT A

CURRICULUM VITAE

Name

Debi Prasad Mukherjee, Sc.D.

Title

Associate Professor and Coordinator of Bioengineering
Department of Orthopaedic Surgery
Louisiana State University Health Sciences Center

Address

1501 Kings Highway, P.O. Box 33932
Shreveport, Louisiana 71130

Telephone: (318) 675-6187
Fax: (318) 675-6186

Date of Birth

October 26, 1939

Family

Wife: Bandana
Sons: Avik
Shomik

Education

1961 B.Ch.E. (Hons), Chemical Engineering, Jadavpur University
1965 S.M., Biochemical Engineering, M.I.T.
1965 S.M., Chemical Engineering, M.I.T.
1967 Ch.E., Chemical Engineering, M.I.T.
1969 Sc.D., Chemical Engineering, M.I.T.
1980 M.B.A., Business Administration, University of Connecticut

Employment History

1992-Present Associate Professor and Coordinator of Bioengineering
Louisiana State University Health Sciences Center, Shreveport, Louisiana

1991-1992 Development Scientist
Union Carbide, Bound Brook, New Jersey

1987 - 1990 Research Program Manager
Dow Corning Wright, Arlington, Tennessee

1974 - 1987 Technical Specialist, Biomaterials
Group Leader, Extrusion & Materials Development
Senior Research Engineer

Davis & Geck, American Cyanamid Company, Danbury, Connecticut

1969 - 1974 Senior Research Engineer
The Goodyear Tire & Rubber Company, Akron, Ohio

Academic Appointment

1989 - 1993 Adjunct Associate Professor, Biomedical Engineering
Memphis State University, Memphis, Tennessee

1992 - Present Adjunct Associate Professor, Biomedical Engineering
Louisiana Tech, Ruston, LA.

Thesis Supervised

1. M.S. Thesis (1992) by J. D. Ray Jr. "A Comparison of Fatigue Behavior for APC-2/AS4 and Comningled PEEK/AS-4 Composite", Dept. of Biomedical Engineering, Memphis State University, Memphis, TN.

2. M.S. Thesis (1992) by R. R. Shults, "A Characterization Study of Hydroxylapatite Coatings on Titanium Alloy Implant Material Before and After Fatigue", Dept. of Biomedical Engineering, Memphis State University, Memphis, TN.

3. M.S. Thesis (1993) by H. A. Mansour, "Bone/Prosthesis Relative Rigidity as an Important Parameter in the Isoelasticity of Total Hip Arthroplasty of the Human Proximal Femur", Department of Biomedical Engineering, Memphis State University, Memphis, TN.

4. M.S. Thesis (1994) by P. R. Menon, "Composites of Hydroxylapatite with Water Soluble or Biodegradable Polymers as a Synthetic Bone Graft Material", Louisiana Tech University, Ruston, LA.

5. M.S. Thesis (1996), by S. Ashroff, "Effect of Crystallinity of Hydroxyapatite Coating on Titanium Implants After Cyclic Fatigue Loading", Louisiana Tech University, Ruston, LA.

6. M.S. Thesis (1996), by N.R. Dorairaj, "Effects of Cyclic Fatigue Loading on the Stability of Hydroxyapatite Coated Titanium Dental Implants in the Presence of the Periodontal Pathogens", Louisiana Tech University, Ruston, LA.

7. M.S. Thesis (1999) by J.R.Hunter, "The measurement of Stress shielding and Relative Rigidity Mismatch within the femur prosthesis union of Total Hip Replacement" Louisiana Tech University, Ruston, LA.

8. Ph.D. Thesis (2001) by Kelly Crittenden, "Evaluation of 135- and 150-degree

Sliding hip screws". Louisiana Tech University, Ruston, LA.

Honors and Awards

1. MNC Memorial Medal for securing the highest grade in the Sophomore Class of the Chemical Engineering Department, 1958.

2. E.F Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A study of burst fracture in a canine model, Louisiana Orthopaedic Association, Harry Morris Award, 1993.

3. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: "Comparison of Fixation of Locking Head and Conventional Screws in Fracture and Reconstruction Models." Winner of American College of Oral and Maxillofacial Surgeons Resident Research Award 18th Annual Meeting, San Diego, CA.,1997.

4. JW Sikes, BR Smith, and DP Mukherjee: "Effect of Bony Buttressing in the Atrophic Edentulous Mandible: An In Vitro Study." Winner of ITI Straumann Research Award, AAOMS 80th Annual Meeting, September 1998.

5. R Bhati, DP Mukherjee, KJ McCarthy, S Rogers, and DF Smith: "The Effect of Fibronectin Coating on the growth of Chondrocytes into a Biodegradable Scaffold." National Student Research Forum- The University of Texas Medical Branch of Galveston Texas, Department of Orthopaedic and Rehabilitation Award, 2000.

Editorial Board

Journal of Long Term Effect of Medical Implants
(Member of Editorial Advisory Board) 1998- Present

Journal of Biomedical Materials Research (Applied Biomaterials)
(Member of Editorial Board) 1998-2002.

Conferences Organized

Akron Polymer Lecture Group

Secretary, 1972
Program Chairman, 1973

14th Southern Biomedical Engineering Conference

Chairman
April 7-9, 1995, Shreveport, LA

Technical Sessions Chaired

Biomaterials:

11th Southern Biomedical Engineering, Memphis, TN (1992), Session Chairman

Determination of Bone Properties:

12th Southern Biomedical Engineering, New Orleans, LA (1993), Session Chairman

Biomechanics and Biomedical Engineering Symposium

Orthopaedics Biomechanics I: 31st Annual Technical Meeting of the Society of Engineering Science, Texas A&M (1994) Session Co-Chairman

Orthopaedic Biomechanics

13th Southern Biomedical Engineering, Washington, D.C. (1994)- Session Chairman

Dental Materials: natural dentition polymers and composites

Sixth World Biomaterials Congress, Hawaii (2000) Session Co-moderator

Polymers in Orthopaedics Symposium (American Chemical Society) August 2002

Chaired the session

Public/Community Service Activities

NIH Proposal Evaluations and Site Visits:

1. Reviewed the contracts on the biocrodible drug-delivery systems and was invited to a site visit to SRI on May 5-7, 1987, by the Contraceptive Development Branch, Center for Population Research, National Institutes of Health and Human Development - NIH contract, Dr. Dinesh Sharma.
2. Reviewed a number of proposal on drug-delivery systems and was invited for a working group in Bethesda, Maryland, on April 27, 1990, NIH contacts, Dr. H. Khan and Dr. D. Sharma.

3. Reviewed proposals on "Development and Testing of New Spermicides for National Institute of Child Health and Development", Bethesda, MD. June 16-17, 1992, NIH contact, Dr. S. Strenfert.
4. Special Study Section - Small Business Innovation Research (SBIR) Program, Rockville, MD, July 6-8, 1994, NIH contact, Dr. N. Vydelingum.
5. Task Group Chair, Scaffold Biomaterials Section, American Society of Testing and Materials (ASTM) 1998- 2001

Institute Activities

1992 - Present	Mentor ;Minority High School Student Research Apprentice Program
1992 - Present	Mentor: Summer Medical Student Research Program
1994 - 1995	Member of the Medical Communication Committee
1998-at present	Mentor: Science Medicine Academic Research Training Program
2001- Present	Flag Group Leader: Module III-New curriculum of instructions to Freshman/Sophomore Medical Students
2003-Present	Member of Institutional Review Board

Invited Lecturer:

Baylor College of Medicine, Department of Orthopaedic Surgery, -Grand Round – Plaster of Paris as a vehicle for delivery of tobramycin to treat Osteomyelitis, March, 13, 1994

Biomaterials Seminar in Atlanta: Technomic Publishing Co. Inc.
Tissue Engineering Applications of Bioabsorbable Polymers, November 16, 1999

Baylor College of Medicine, Department of Orthopaedic Surgery, - Grand Round Baylor University Medical center, Houston, TX, Meniscal Repair, May 7, 2003

Society Membership

Orthopaedic Research Society
Society for Biomaterials
American Association of Advancement of Science

Research Support and Meeting Grants

1. American Heart Association, Akron Chapter, December 10, 1973, for the project, The Relationship of Dynamic Mechanical Properties of Arteriosclerotic Tissue to the Deposit of Cholesterol and Its Ester, jointly with Dr. Thomas Pynadath of Kent State University, Kent, Ohio 44242, $8030.00

2. School of Dentistry, LSU Medical Center, and New Orleans. "Biomechanical In Vitro testing of the stability of HA coating etc.", jointly with Dr. J. Wittenberg, Department of Surgery, Division of Oral and Maxillofacial Surgery LSUMC-S, 1993, $7500.00.

3. ExacTech Inc., Gainesville, FL. "Experimental testing of components comprising the ExacTech 913 Knee System." 1993, $150.00

4. Whitaker Foundation: Fourteenth Southern Biomedical Engineering Conference, 1994, $6,000.00.

5. Smith & Nephew Richards: Fourteenth Southern Biomedical Engineering Conference, 1994, $1,000.00.

6. Sofamor Danek Medical: Fourteenth Southern Biomedical Engineering Conference, 1994, $300.00.

7. Dean - LSU School of Medicine-Shreveport: Fourteenth Southern Biomedical Engineering Conference, 1994, $4,500.00.

8. Center of Excellence for Arthritis & Rheumatology: 1992-1994, $37,070.00

9. Ortho-Care, Inc: 1994, $550.00.

10. Chitogenics, Inc.: Nov. 1995-May 1996, Evaluation of the carboxymethyl chitosan (NOCC) and hydroxyapatite composite paste for repairing bone defects in a rat model. Feasibility of using NOCC to complex with the hyaluronic acid to reduce the drop of viscosity of synovial fluids of the rheumatoid patients. $10,000.00.

11. Intramural Grant: January 1, 1997 - December 31, 1997. Tissue Engineering - Development of Scaffolds seeded with Different Cell types on a biodegradable matrix. $5,000.00.

12. Wright Medical Technology: June 15, 1997 - Feb. 1999. Measurement of Creep Properties of Bone Cement. $15,000.00

13. Louisiana Board of Regents: Travel Grant for Emerging Faculty. $500.00.

14. Celanese Acetate: November, 15, 1998- November 15, 1999. Feasibility study of modification of cellulose acetate filters (CAF) by gamma and electron beam radiations. $7,060.00.

15. Board of Regents Support fund, June 2000-June 2001 with matching grant from LSUHSC: Replacement of Biaxial Testing machine (Instron Model 1321) by a new digital biaxial machine (Model 8874): **$117,732.**

16. Clinical and Industrial technology Company, July 2000- July 2001: A New Vibration Mixer for Bone Cement: **$14,000.**

17. Department of Obstetrics & Gynecology , 2002-2003: "Biomechanical Studies on several Sutures". **$3420.**

18. W.L.Gore and Associates, Biodegradable Scaffold for Tissue Engineering , Jan -May 2004, **$5000.**

PUBLICATIONS

Research Thesis

D. P. Mukherjee, The Viscoelastic Properties of Elastin, Sc.D. Thesis in the Department of Chemical Engineering, M.I.T., January 13 (1969).

Papers and Abstracts of Presentations

1. DP Mukherjee and A.S. Hoffman: The Viscoelastic Properties of Elastin. Presented at the Third Biophysics Congress, August (1969).

2. A.S. Hoffman and DP Mukherjee: long-range Interactions of Cationic Sites in Elastin. Presented at the Conference on Engineering in Medicine and Biology, October 31(1971).

3. DP Mukherjee and C. Goldstein: The Mechanical and Optical Properties of Alternating and Random Copolymers of Acrylonitrile and Butadiene at the Same Acrylonitrile Content. Polymer Preprints, Vol. 14, No. 1, 36-39, (1973).

4. DP Mukherjee and C Goldstein: The Mechanical and Optical Properties of an Alternating and Emulsion NBR. Rubber Chemistry and Technology, 46, 1264-1273, (1973).

5. DP Mukherjee, AS Hoffman, and C Franzblau: The Physical Properties and Molecular Structure of Ligamentum Nuchae Elastin. Biopolymer, Vol. 13, 2447-2459, (1974).

6. DP Mukherjee and MC Morris: Rheological Properties of Synthetic Poly (isoprene) and Natural Rubber. Presented at the Annual Meeting of the Society of Rheology, Amherst, Massachusetts, October, (1974).

7. DP Mukherjee: Simultaneous Stress-Strain and Stress-Birefringence Studies on Natural Rubber, Isomerized Natural Rubber and Synthetic Poly (isoprene). Rubber Chemistry and Technology, Vol..47, No. 5,1234-1240, (1974).

8. DP Mukherjee, H.M. Kagan, R.E. Jordan, and C. Franzblau: Effect of Hydrophobic Elastin Ligands on the Stress-Strain Properties of Elastin Fibers. Connective Tissue Research, 4, No. 3, 177-179, (1976).

9. DP Mukherjee and TI Pynadath: The Relationship of Dynamic Mechanical Properties of Arteriosclerotic Tissue of Cholesterol and Cholesterol Ester Levels of Serum and Aortic Tissues During Early Stages of Development of Atherosclerosis. Atherosclerosis, 26, 311-318, (1977).

10. DP Mukherjee: A Study of Flow Properties of Rubbers Using Rheometrics Mechanical Spectrometer. Polymer Engineering and Science, November 17, No. 1, 788-792, (1977).

11. AR Katz, D.P. Mukherjee, AL Kaganov, and S Gordon: A New Synthetic Monofilament Absorbable Suture Made from Polytrimethylene Carbonate. Surgery. Gynecology and Obstetrics, September, Vol. 161, 213-222, (1985).

12. DP Mukherjee and C Sandock: Effect of Gamma Irradiation on the Properties of the Glycolide/Trimethylene Carbonate Copolymer Maxon® Suture. The Third World Biomaterials Congress, April 21-25, 1988, Kyoto, Japan.

13. DP Mukherjee and JG Brooks, Jr.: Mechanical and Non-Destructive Evaluations of a Carbon/Carbon Composite Material. 37th Annual Meeting, Orthopedic Research Society, March 4-7,1991, Anaheim, California, 498.

14. DP Mukherjee and S Saha: Isoelasticity: A Design Consideration of Total Hip Replacement. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 25-27.

15. S Saha and DP Mukherjee: Use of Composite Materials for Total Hip Arthroplasty. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 93-96.

16. JD Ray and DP Mukherjee: A Comparison of Fatigue Properties of Carbon Fiber/PEEK Composites. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 142-144.

17. RR Shults, DP Mukherjee, and JD Ray: A Study of Hydroxylapatite Coated Titanium Alloy Material After Fatigue. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 159-161.

18. JJ Lorio, RN Kruse, DP Mukherjee, and JA Albright: Compressive Strength and Quantitative CT Measurements of Cancellous Bone Sample. 34th National Student Research Forum. The University of Texas Medical Branch, Galveston, Texas, April 15-17, 1993.

19. JJ Lorio, RN Kruse, DP Mukherjee, and JA Albright: Quantitative Computer Tomography (QCT) and Mechanical Properties of Cancellous Bone. Proceedings of the Twelfth Southern Biomedical Engineering Conference, New Orleans, LA, April 2-4, 1993, pp 242-244.

20. RN Kruse, DP Mukherjee, and JA Albright: A Method of Quantitative Analysis of Computed Tomography (QCT) Scan of Bone Samples Using a Sun Workstation. Proceedings of the Twelfth Southern Biomedical Engineering Conference, New Orleans, LA, April 2-4, 1993, pp 37-39.

21. DP Mukherjee, T Sweo, and JA Albright: A Comparative Study of Femoral Neck Fracture Fixation by a Compression Screw or Knowles Pins. First Joint ASCE/ASME

Summer Meeting and SES 30th Annual Meeting: Biomaterials and Biomechanics Symposium, Charlottesville, VA, June 6-9, 1993, pp 61.

22. DP Mukherjee and S. Saha: The Application of New Composite Materials for Total Joint Arthroplasty. Journal of Long Term Effects of Medical Implants, 3 (2): 131-141 (1993).

23. AD McBride, DP Mukherjee, RN Kruse, and JA Albright: Anterior Screw Fixation of Type II Odontoid Fractures: A Biomechanical Study. Poster presentation 21st Cervical Spine Research Society Meeting, New York, December 1-4, 1993.

24. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: Relationship Between Bone Mineral Density and Burst Fracture Load: A Biomechanical Study. Transactions of Orthopaedic Research Society, 19(2): 530, 1994.

25. DP Mukherjee, JM Wittenberg, SH Rogers, RN Kruse, and JA Albright: Surface Changes of Hydroxyapatite Coated Dental Implants After Cyclic Loading. Transactions 20th Annual Meeting of the Society for Biomaterials, 17:7, 1994.

26. JD Ray Jr., DP Mukherjee, and JD Ray: The Fatigue Properties of Carbon Fiber/PEEK Composites: Transactions 20th Annual Meeting of the Society for Biomaterial, 17:161, 1994.

27. RR Shults, DP Mukherjee, and JD Ray: A Study of Fatigue Properties of Hydroxyapatite Coated Titanium Alloy Implant Materials. Transactions 20th Annual Meeting for the Society for Biomaterials, 17:333, 1994.

28. DP Mukherjee, S Rogers, S Foster, KK Sadasivan, and JA Albright: A Histological Study of Polyethylene Particles in a Rabbit Model. Transactions of the 20th Annual Meeting of the Society for Biomaterials, 17:392, 1994.

29. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Comparative Biomechanical Evaluation of the Thoracolumbar Burst Fracture in Human and Canine Specimens. Orthopaedic Transactions, J Bone Joint Surg., 18(2): 517, 1994.

30. AD McBride, DP Mukherjee, RN Kruse, and JA Albright: A Biomechanical Study of Anterior Screw Fixation of Type II Odontoid Fractures. Poster Presentation, North American Spine Society and Japanese Spine Research Society, Spine Across the Sea, Maui, Hawaii, April 18-21, 1994.

31. J.E. Broyles, DP Mukherjee, and JA Albright: Application of the Photoelastic Coating Technique to Measure Strain in the Talar Neck. 35th Annual National Student Research Forum, University of Texas Medical Branch at Galveston, TX, 79, April 28-30, 1994.

32. RF Favret, DP Mukherjee, RN Kruse, and JA Albright: Analysis of Compressive Strength and Dual X-ray Absorptiometry Evaluation of Cancellous Bone Grafts. Biomedical

Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 158-161.

33. W Johnson, C.M Hymel, DP Mukherjee, and JA Albright: Crosslink Density and Water Content in Intervertebral Discs. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 689-692.

34. D York, DP Mukherjee, SH Rogers, AW Pearsall, KK Sadasivan, and JA Albright: An Evaluation of Implants and Tissues Retrieved After Orthopaedic Surgery. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 736-738.

35. PR Menon, RL Seaman, and DP Mukherjee: Development of a Composite of Polyethylene Oxide and Hydroxyapatite as a Bone Graft Substitute. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 772-774.

36. JE Broyles, RN Kruse, DP Mukherjee and JA Albright: Application of the Photoelastic Coating Technique to Measure Strain in the Talar Neck. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 856-859.

37. DP Mukherjee, SQ Hayat, C Mocek, S Foster, V Hall, and RE Wolf: Shear Viscosity and Cytokines in Rheumatoid Synovial Fluids. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 1081-1084.

38. SQ Hayat, V Hall, DP Mukherjee, and RE Wolf: Cytokines in rheumatoid Arthritis: Synovial Fluid and Serum Levels. Presented at the American College of Rheumatology Regional Meeting, May 13-15, 1994.

39. S Saha and DP Mukherjee: Use of Composite Materials for Total Joint Replacement. Proceedings of the 31st Annual Technical Meeting of the Society of Engineering Science, Biomechanics and Biomedical Engineering Symposium, Texas A&M University, October 10-12, 1994, pp 125.

40. H Mansour, JD Ray, M Yen, and DP Mukherjee: A biomechanical Study of Stress Shielding of the Femoral Component of Orthopaedic Hip Implants. Proceedings of the 31st Annual Technical Meeting of the Society of Engineering Science, Biomechanics and Biomedical Engineering Symposium, Texas A&M University, October 10-12, 1994, pp 171.

41. JM Wittenberg, DP Mukherjee, and BR Smith: Biomechanical Evaluation of a New Fixation Device for Mandibular Angle Fractures. Supplement to Journal of Oral and Maxillofacial Surgery, 52(B), Suppl. 2, Aug. 1994, pp 107.

42. W Johnson, C.M Hymel, DP Mukherjee, and JA Albright: Crosslink Density and Water Content in Intervertebral Discs. Journal of Long-Term Effects of Medical Implants, 4(1): 20, 1994

43. J.E. Broyles, RN Kruse, DP Mukherjee, and JA Albright: Application of the Photoelastic Coating Technique to Measure Strain in the Talar Neck. Journal of Long-Term Effects of Medical Implants, 4(1): 21-22, 1994.

44. DP Mukherjee, SQ Hayat, C Mocek, S Foster, V Hall, and RE Wolf: Shear Viscosity and Cytokines in Rheumatoid Synovial Fluid. Journal of Long-Term Effects of Medical Implants, 4(1): 23, 1994.

45. PR Menon, RL Seaman, and DP Mukherjee: Development of a Composite of Polyethylene Oxide and Hydroxylapatite as a Bone Graft Substitute. Journal of Long-Term Effects of Medical Implants, 4(1): 40, 1994.

46. AD McBride, DP Mukherjee, RN Kruse, and JA Albright: Anterior Screw Fixation of Type II Odontoid Fractures: A Biomechanical Study. Spine, 20(17) No1: 1855-1859, 1995.

47. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Thoracolumbar Pedicle Screw Fixation with Zero, 1 or 2 Crosslinks. AOA Resident Conference in Pittsburgh, Mar. 1995.

48. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Method to Characterize Burst Fractures. AOA Resident Conference in Pittsburgh, Mar. 1995.

49. DP Mukherjee, J.M. Wittenberg, SH Rogers, RN Kruse, and JA Albright: A Fatigue Study of Hydroxyapatite Coated Dental Implants. Transactions of the 21st Annual Meeting of Society for Biomaterials, 18, 283, 1995.

50. MP Langford, JA Schulman, DP Mukherjee, and JP Ganley: Effects of Vitreal Substitutes (Healon, Chitosan and Vitreon) on Epithelial Cells and Human Peripheral Blood Lymphocytes. Proceedings of the 14th Southern Biomedical Engineering, 286-288, 1995.

51. K Coward, B Smith, RN Kruse, and DP Mukherjee: A Biomechanical Study of Mandibular Fracture Fixation Plates in a Bovine Rib Model. Proceedings of the 14th Southern Biomedical Engineering Meeting, 87-89, 1995.

52. JM Wittenberg, BR Smith, RN Kruse, and DP Mukherjee: A Study of Mandibular Fracture Fixation by Different Plate Designs. Proceedings of the 14th Southern Biomedical Engineering Meeting, 46-48, 1995.

53. G. Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: A Biomechanical Study of 150 vs 135-Degree Hip Screws in Femoral Neck Fractures. Proceedings of the 14th Southern Biomedical Engineering Meeting, 49-50, 1995.

54. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Method to Characterize Burst Fractures. Proceedings of the 14th Southern Biomedical Engineering Meeting, 51-52, 1995.

55. HA Mansour, JD Ray, and DP Mukherjee: Stress Shielding of Femoral Hip Components With and Without Collar. Proceedings of the 14th Southern Biomedical Engineering Meeting, 53-54, 1995.

56. SM Atchison, DP Mukherjee, RN Kruse, R Mayeux, and JA Albright: Internal Fixation of Transverse Acetabular Fractures. Proceedings of the 14th Southern Biomedical Engineering Meeting, 55-56, 1995.

57. RB Lurate, DP Mukherjee, RN Kruse, and JA Albright: Fixation of Osteochondral Fractures with Absorbable Pins. Proceedings of the 14th Southern Biomedical Engineering Meeting, 57-58, 1995.

58. PR Menon, SA Napper, and DP Mukherjee: Development of a Composite Hydroxylapatite and Chitosan as a Bone Graft Substitute. Proceedings of the 14th Southern Biomedical Engineering Meeting, 95-97, 1995.

59. DP Mukherjee, D Smith, V Hall, and RE Wolf: Relationship of Viscosity and Hyaluronic Acid Content and Molecular Weight in Synovial Fluids of Rheumatoid Arthritis Patients. American College of Rheumatology, 38, No. 6 (Supplement), R23, June 1995.

60. Eric F Berkman, Debi P Mukherjee, and James A Albright: Plaster of Paris as a Vehicle for Tobramycin. Musculoskeletal Infection Society Annual Meeting, Snow Mass, Colorado, August 10-12, 1995.

61. DP. Mukherjee, RF Favret, RN Kruse, JA. Albright, and AB Chausmer: Compressive Strength and Bone Mineral Density (DEXA) of Trabecular Bone From Vertebral Bodies. American Society for Bone and Mineral Research, 17th Annual Meeting, Baltimore, Maryland, September 10, 1995.

62. MP Langford, Joel A Schulman, Debi P Mukherjee, and James P Ganley: Effects of Healon ®, N1O Carboxyl Methyl Chitosan and Vitreon on Conjunctival Cells and Human Peripheral Blood Lymphocytes. Journal of Long Term Implants, Vol 5 (1), 1995.

63. PR Menon, SA Napper, and DP Mukherjee: Development of a Composite of Hydroxylapatite and Chitosan as a Bone Graft Substitute. Journal of Long Term Implants, Vol 5 (1), 1995.

64. JA Albright, E.F Berkman, and DP Mukherjee: Plaster of Paris as a Vehicle for Tobramycin. Biomedical Engineering Society, Annual Fall Meeting, Boston, Oct. 6-8, 1995.

65. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Mechanical Stability of Thoracolumbar Pedicle Screw Fixation with Two, And Zero Crosslinks. Biomedical Engineering Society, Annual Fall Meeting, Boston, Oct. 6-8, 1995.

66. D Mukherjee, R Favret, R Kruse, JA Albright, and AB Chausmer: Correlation of Compressive Strength of Trabecular Bone of Vertebral bodies to Bone Mineral Density by Dual Energy X-ray Absorptiometry (DEXA). Transactions of the 2nd Combined Meeting of the Orthopaedic Research Societies of U.S.A., Japan, Canada and Europe, Nov. 5-8, 244, 1995.

67. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Thoracolumbar Pedicle Screw Fixation with Zero, 1 or 2 Crosslinks. Orthopaedic Transactions (The Journal of Bone and Joint Surgery) 19(3), 727, 1995-96.

68. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Method to Characterize Burst Fractures. Orthopaedic Transactions (Journal of Bone and Joint Surgery), 19(3), 731, 1995-96.

69. S Ashroff, SA Napper, PN Hale Jr., U Siriwardane, and DP Mukherjee: Stability of Hydroxyapatite Coating of Different Crystallinities on a Titanium Alloy Implant Material After Cyclic Fatigue. Proceedings of the Fifteenth Southern Biomedical Engineering Conference, 14-17, 1996

70. G Germany, S Rogers, and DP Mukherjee: A Histological Study of Polyethylene Wear Particles in a Rabbit Model. Proceedings of the Fifteenth Southern Biomedical Engineering Conference, 178-199, 1996.

71. S Mukherjee, SH Rogers, RH Mayeux, and DP Mukherjee: A Study of Achilles Tendon Rupture. Proceedings of the Fifteenth Southern Biomedical Engineering Conference, 381-383, 1996.

72. DP Mukherjee, SH Rogers, KK Sadasivan, D.G. Schmidt, MA Meyer, and JA Albright: Effects of Polyethylene Particles on Rabbit Knee Joints. Transactions of the Fifth World Biomaterials Congress, May 29-June 2, 902, 1996.

73. TC Mitchell, DP Mukherjee, and JA Albright: Plaster of Paris as a Vehicle for Vancomycin. Musculoskeletal Infection Society, August 1-3, 1996.

74. DP Mukherjee, E.F Berkman, TC Mitchell, and JA Albright: Treatment of Osteomyelitis by Tobramycin Impregnated Plaster of Paris, Musculoskeletal Infection Society, August 1-3, 1996.

75. S Ashroff, SA Napper, PN Hale Jr., U Siriwardane, and DP Mukherjee: Cyclic Fatigue of Hydroxyapatite Coated Titanium Alloy Implant Material - Effect of Crystallinity. J of Long-Term Effects of Medical Implants, 6(3&4):143-155, 1996.

76. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: Comparison of Fixation Strength between Reconstruction Plates with Locking-Head and Conventional Screws. J. Oral Maxillofacial Surg. 54(Suppl. 3); 39-40, 1996.

77. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: Comparison of the Fixation Strength between Reconstruction Plates with Conventional and Locking-Head Screws. Oral Abstract, American Association of Oral and Maxillofacial Surgeons National Meeting, Miami, FL., Sept. 18, 1996.

78. M Pearson, DP Mukherjee, F Mire, and AB Chausmer: A Method To Evaluate a Synthetic Bone Growth Material in A Rat Model Using Dual Energy X-ray Absorptiometry (DEXA). Poster presentation Intramural Society for Clinical Densitometry. January 16-19, 1997.

79. CD Clark, RH Mayeux, M Palmer, DP Mukherjee, KK Sadasivan, and JA Albright: A Biomechanical Evaluation of a Posterior Glenohumeral Lesion. Orthopaedic Transactions (ORS), J Bone Joint Surg, 20(3): 800, 1996-1997.

80. DP Mukherjee, JA Albright, AW Pearsall, RH Mayeux, and WM Palmer: A Biomechanical Study of Posterior Cruciate Ligament Fixation. Scientific Exhibit American Academy of Orthopaedic Surgeons, 64th Annual meeting, February 13-17, 1997.

81. NR Dorairaj, D.Mills, RD Berg, DP Mukherjee, and JA Albright: Cyclic Fatigue of Hydroxyapatite Coated Titanium Alloy Dental Implants after Exposure to a Periodontal Pathogen. Transactions of 43rd Annual Meeting Orthopaedic Research Society, 756, 1997.

82. SR Blair, RH Mayeux, AL Ogden, DP Mukherjee, KK Sadasivan and JA Albright: Glenohumeral Stability of the Shoulder, the Role of Labrum, Coracoid and Acromion. Transactions of 43rd Annual Meeting Orthopaedic Research Society, 882, 1997.

83. J.M Wittenberg, DP Mukherjee, BR Smith, and RN Kruse: Biomechanical Examination of New Fixation Devices for Mandibular Angle Fractures. Int. J. Oral Maxillofac. Surg., 26:68-73, 1997.

84. CD Clark, RH Mayeux, M Palmer, DP Mukherjee, KK Sadasivan, JA Albright: A Biomechanical Evaluation of a Posterior Glenohumeral Lesion. Orthopaedic Transactions (AOA Residents Conference), J Bone Joint Surg., 20(4): 880, 1996-1997.

85. AL Ogden, RH Mayeux, and DP Mukherjee: Wear Properties of Ultra High Molecular Weight Polyethylene Material. Proceedings of the Sixteenth Southern Biomedical Engineering Conference, pp 84-87, April 4-6, 1997.

86. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Mechanical Stability of Thoracolumbar Pedicle Screw Fixation: The Effect of Crosslinks. Spine, 22(14): 1568-1573, 1997.

87. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: The Effect of Bony Buttressing on Fixation Strengths of Locking Head and Conventional Screws in Both a Fracture and Reconstruction Model. American College of Oral and Maxillofacial Surgeons, 18th Annual Conference, Oral Abstract presentation, Mar. 20-23, 1997.

88. DP Mukherjee, M Pearson, SH Rogers, and P. Menon.: In Vitro and In Vivo Evaluations of a New Synthetic Bone Graft Material. Material Research Society, Symposium O: Polymers in Orthopaedics, December 3-4, 1997, Boston, pp. 350.

89. JA Albright, EF Berkman, TC Mitchell, and DP Mukherjee: Plaster of Paris for Delivery of Antibiotics in Osteomyelitis Poster Presentation, 10th Combined Meeting Orthopaedic Associations of the English Speaking World, February 1-6, 1998, Auckland, New Zealand.

90. DP Mukherjee, S Ashroff, NR Dorairaj, S Rogers: Surface Morphology of the Hydroxyapatite Coated Titanium Alloy Implant Material Subjected to Fatigue in the Presence of a Periodontal Pathogen. Proceedings of the 17th Southern Biomedical Engineering Conference, 123, 1998.

91. DP Mukherjee, DF Smith, SH Rogers, and JA Albright: Cell Seeding on a Biodegradable Scaffold Material. Transactions of the Society for Biomaterials, 21:541, 1998.

92. KA Coward, BR Smith, and DP Mukherjee: Comparison of Mandibular Fracture Fixation Techniques. J of the Louisiana State Medical Society, 149(11): 427, 1997.

93. M. Pearson and DP Mukherjee: In Vivo Evaluation of Hydroxyapatite (HA)/N,O Carboxyl Methyl Chitosan (NOCC) Paste in a Rat Model. J of Louisiana State Medical Society, 149(11): 431, 1997.

94. JW Sikes Jr., BR Smith, DP Mukherjee, and KA Coward: Comparison of Fixation Strengths of Locking Head and Conventional Screws in Fracture and Reconstruction Models. J. Of Oral and Maxillofacial Surgery, 56:468-473, 1998.

95. NR Dorairaj, D Mills, RD Berg, DP Mukherjee, and JA Albright: Cyclic fatigue of hydroxyapatite coated titanium alloy dental implants after exposure to a periodontal pathogen. Orthop Trans, JBJS, 21(3): 1008, 1997-1998.

96. SR Blair, RH Mayeux, AL Ogden, DP Mukherjee, KK Sadasivan, and JA Albright: Glenohumeral stability of the shoulder: Role of labrum, coracoid and acromion. Orthop. Trans, JBJS, 21(3): 1071, 1998.

97. MR Wiedmer, DP Mukherjee, JR Green, RH Mayeux, AL Ogden, KK Sadasivan, and JA Albright: Influence of the anterior labrum on the anterior-posterior translation of the shoulder. Transactions, Orthop. Research Society 45th Annual Meeting, pp 379, 1999.

98. RP Texada, DP Mukherjee, RH Mayeux, AL Ogden, KK Sadasivan, and JA Albright: Thoracolumbar fracture fixation: A novel arrangement of crosslinks. Transactions of Orthopaedic Research Society 45th Annual Meeting, pp 992, 1999.

99. HJ Granger, JR Green, DP Mukherjee, AL Ogden, and RH Mayeux: The security of a new arthroscopic knot. American Academy of Orthopaedic Surgery, Poster #396, 1999.

100. DP Mukherjee, M Pearson, R Roberts, SH Rogers, JA Albright, and AB Chausmer: Development of an experimental protocol for animal evaluations of a composite of hydroxyapatite and a water-soluble polymer. Transaction Society for Biomaterials, 22: 350, 1999.

101. DP Mukherjee, SH Rogers, D Smith,and SW Shalaby: A comparison of chondrocyte cell growth in a biodegradable scaffold with and without mixing. Transaction Society for Biomaterials, 22: 528, April 28-May 2, 1999.

102. DP Mukherjee, AL Ogden, RH Mayeux, U.Siriwardane and H. Patel: Effect of carbon coating on the properties of gamma irradiated ultrahigh molecular weight polyethylene specimens. Eighteenth Southern Biomedical Engineering Conference, May 20-23, 1999

103. TC Mitchell, KK Sadasivan, AL Ogden, RH Mayeux, DP Mukherjee, and JA Albright: Biomechanical Study of Atlantoaxial Arthrodesis: Transarticular Screw Fixation Versus Modified Brooks Posterior Wiring. J. of Orthopaedic Trauma, 13 (7): 483-489, 1999.

104. JW Sikes Jr., BR Smith, and DP Mukherjee: An invitro study of the effect of bony buttressing on fixation strength of a fractured atrophic edentuous mandible model. J. of Oral and Maxill. Surg., 58(1): 56-61, 2000.

105. R Bhati, DP Mukherjee, KJ McCarthy, S Rogers, and DF Smith: The effect of fibronectin coating on the growth of chondrocytes into a biodegradable scaffold. Abstract '41 ST National Student Research Forum, The University of Texas Medical Branch at Galveston, April 6-8, #B-4, 48, 2000.

106. KAnjali Danese, Debi P Mukherjee, Dollie Smith, Kalia K. Sadasivan, and James A Albright: Effect of Chitosan Glutamate on osteoblasts *in vitro*. Sixth World Biomaterials Congress Transactions, Vol. II, 978, 2000.

107. Debi P.Mukherjee, Shelia H Rogers, and Olubunmi T Lampejo: The reaction of polyethylene particles to tissues- an animal study. Sixth World Biomaterials Congress Transactions, Vol. II, 1480, 2000.

108. Debi P. Mukherjee, Nanda Kumar R. Dorairaj, David K. Mills, David Graham, and Jack T. Krauser: Fatigue properties of hydroxyapatite coated dental implants after exposure to a periodontal pathogen. J. Biomedical Materials Research (Applied Biomaterials), 53 (5) 467-474, 2000

109. Albert W. Pearsall, Ray H. Mayeux, Debi P. Mukherjee, and James A Albright: The effect of isometric graft posterior cruciate ligament reconstruction on anterior tibial translation. Orthopaedics, 28(6) June, 567-570, 2000.

110. Debi P Mukherjee, Dollie Smith, Richard Roberts, Sam Tunkle, and Andrew Clavenna: Evaluation of chitosan glutamate paste to repair bone defects. Annual Fall Meeting Biomedical Engineering Society, October 12-14, 2000.

111. R. S. Bhati, D. P. Mukherjee, K. J. McCarthy, S. H. Rogers, D. F. Smith, and S. W. Shalaby: The growth of chondrocytes into a fibronectin-coated biodegradable scaffold. J. Biomed Mater Res 56: 74-82, 2001.

112. Debi P. Mukherjee, Shane Smith, Michael Hartman, Shelia Rogers, Alan L. Ogden , Ray H Mayeux, and Judy Tedenton. An in-vivo evaluation of Plaster of Paris in a critical size defect model. Transaction Society for Biomaterials, 27: 415, April 24-29, 2001.

113. Debi P. Mukherjee, A S Tunkle, R. A Roberts, A Clavenna, S. Rogers, and J. Tendenton. Evaluation of a paste of chitosan glutamate and hydroxyapatite as a synthetic bone graft material. Transaction Society for Biomaterials, 27: 285, April 24-29, 2001.

114. Lois A. Nichols, Debi P. Mukherjee, Alan L. Ogden, Ray H. Mayeux, and Karl K. Bilderback, Atlantoaxial Arthrodesis by Unilateral Transarticular Screw- A Biomechanical Study, Cervical Spine Research Society, 29 th Annual Meeting, 201, Nov. 29-Dec 1,201, 2001

115. Solomon H. Chaim, Debi P. Mukherjee, Alan L. Ogden, Raymond H. Mayeux, Kalia K. Sadasivan, and James A Albright. A biomechanical study of femoral neck fracture fixation with the VHS®Vari-Angle Hip fixation system The American Journal of Orthopaedics, vol XXXI, (1S), 22-24, 2002.

116. Daniel C. Schubert, James B. Unger, Debi P. Mukherjee, and Jack P.Perrone. Mechanical performance of knots using braided and monofilament absorbable sutures. Society of Gynecologic Surgeons, 28 th Annual Scientific meeting, March 4-6, 2002.

117. Tim Talbert, Debi Mukherjee, Raymond Mayeux, Alan Ogden, and John Green. Bioabsorbable Screw Fixation in Coracoclavicular Ligament Reconstruction. Transactions 48th Annual Meeting Orthopaedic Research Society, February 10-13, 841,2002.

118. Thomas Hansen, Debi P. Mukherjee, Raymond H. Mayeux, Alan L. Ogden, Kalia K. Sadasivan, and James A. Albright. A biomechanical study of biodegradable screw fixation of medial malleolar fracture. Polymer Preprints , ACS meeting August 20,2002.

119. Daniel C. Schubert, James B. Unger, Debi Mukherjee, and Jack F. Perrone. Mechanical performance of knots using braided and monofilament absorbable sutures. Am J. of Obstet Gynecol, 187-, 2002.

120. D. P. Mukherjee, A S Tunkle, R. A Roberts, A Clavenna, S. Rogers, and D. Smith. Evaluation of a paste of chitosan glutamate and hydroxyapatite as a synthetic bone graft material. J Biomedical Materials Research Part B: Applied Biomaterials, 67B: 603-609, 2003.

121. M. Wiedmer, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux and J. R. Green. A Biomechanical Evaluation of the Role of Labrum on Anterior/Posterior translation of Shoulders at Different Degrees of Abduction. J. of Long-Term effects of Medical Implants, 13 (4), 309-318, 2003.

122. Timothy W. Talbert, John R. Green, Debi P. Mukherjee, Alan L. Ogden , R. H. Mayeux. Bioabsorbable Screw Fixation in Coracoclvicular Ligament reconstruction. J. of Long-Term effects of Medical Implants, 13 (4), 319-323, 2003.

123. S. Cox, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux, K. K. Sadasivan, J A. Albright. Syndesmosis fixation by a bioabsorbable screw, Transaction Society for Biomaterials, 29: 602, April 30-May 3, 2003

124. E. Walker, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux, K. K. Sadasivan, J A. Albright. Femoral Neck Fracture Fixation by Cannulated Screws. Poster Presentation 50 th Annual Meeting of Orthopaedic Research Society, San Francisco, March 7-10, 2004.

125. J. Anderson, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux, K. K. Sadasivan. Repair of Meniscal Tear by Sutures or Devices. Poster Presentation 50 th Annual Meeting of Orthopaedic Research Society, San Francisco, March 7-10, 2004.

126. Joseph J. Ivy[1], James B. Unger[1], Debi Mukherjee. Knot Integrity with Non-Identical and Parallel Sliding Knots. American Journal of Obstetrics and Gynecology,190, 83-86, 2004 [[1]Division of Pelvic Surgery, Department of Obstetrics and Gynecology]

127. M. U.Burney, D. P. Mukherjee , A.l. Ogden , R. E. McCall. The Effects of crosslinks on the pedicle screw fixation of scoliosis, Presented in the International Meeting on Advanced spine Techniques (IMAST), Bermuda July 1-4, 2004.

128. S. Cox , D..P. Mukherjee, A. L Ogden, R H Mayuex, , K. K Sadasivan, , J. A. Albright, W.S. Pietrzak . Distal Tibio-fibular Syndesmosis Fixation: A Cadaveric, Simulated Fracture Stabilization Study Comparing Bioabsorbable and Metallic Single Screw Fixation, J. Foot and Ankle Surgery, 44(2) ,144-151, 2005.

129. L. A. Nichols, D. P. Mukherjee, A. L. Ogden, K. K Sadasivan, J. A Albright. A Biomechanical Study of Unilateral Posterior Atlantoaxial Transarticular Screw Fixation , J. of Long-Term effects of Medical Implants, 15(1), 33-38, 2005.

130. K.J. Collins, D.P. Mukherjee , A.L. Ogden, E. Robinson, K.K. Sadasivan, J.A. A Bankart Lesion Fixation- Biodegradable POP Rivet Fixator vs. Suture Repair Poster presentation in the 51st Annual Meeting of the Orthopaedic Research Society, February 20-23, 2005, in Washington, DC.

131. M. Umar Burney, Debi P. Mukherjee, Alna L. Ogden, Errin Robinson, Richard E. McCall. A Biomechnaical study of posterior spinal instrumentation using pedicle crews with and without cross-links. J of Spinal Disorders &Techniques, 2005,18(4), 364-368 .

132. D. P. Mukherjee, D. F. Smith, S. H. Rogers, B. K. Hayes. Evaluation of A bioabsorbable PGA:TMC scaffold for growth of chondrocytes. Transactions 30th Annual Meeting Soc. for Biomaterials , Memphis , TN, April 27-30, 2005 , page 12.

133. D. P. Mukherjee, D. F. Smith, S. H. Rogers, B. K. Hayes. Growth of chondrocytes and extracellular matrix production in a bioabsorbable scaffold. Transactions 30th Annual Meeting Soc. for Biomaterials , Memphis , TN, April 27-30, 2005 , page 11.

Chapter in Book

1. DP Mukherjee and AS Hoffman: Physical and Mechanical Properties of Elastin. Biophysical Properties of the Skin, H.R. Elden (ed.) John Wiley and Sons, Incorporated, New York, 1971, pp. 219-241.
2. Debi P. Mukherjee, William S. Pietrzak Bioabsorbable Fixation: Scientific and Clinical Concepts- Submitted to Orthopedic Implants : Applications, Complications, and Management, R.W.Lindsey and Z. Gugala, Maercel Decker , Inc. Publisher, June 2, 2004.

Review

DP Mukherjee: A Review on Sutures. Encyclopedia of Polymer Science and Engineering, Vol. 16, 2nd Edition, John Wiley and Sons, pp. 473-487, (1989).

Patent

1. Debi P Mukherjee and Kurt A Feichtinger: Process for Manufacturing A Molded Prosthetic Device. U.S. Patent No. 4,808,351, February 28 1989.
2. Debi P. Mukherjee : Method for Producing Chitin or Chitosan. U.S. Patent No. 6,310,188 B1, October 30, 2001.

EXHIBIT B

(1)

Engineers' Guide to Composite Materials

John W. Weeton
Consultant
Formerly Chief of Composite Materials Branch at NASA

Dean M. Peters
Consultant

Karyn L. Thomas
ASM Editorial Staff

American Society for Metals
Metals Park, Ohio 44073

This book is a collective effort involving a large number of technical specialists. It brings together a wealth of information from world-wide sources to help scientists, engineers, and technicians solve current and long-range problems.

Great care is taken in the compilation and production of this book, but it should be made clear that no warranties, express or implied, are given in connection with the accuracy or completeness of this publication, and no responsibility can be taken for any claims that may arise.

Nothing contained in this book shall be construed as a grant of any right of manufacture, sale, use, or reproduction, in connection with any method, process, apparatus, product, composition, or system, whether or not covered by letters patent, copyright, or trademark, and nothing contained in this book shall be construed as a defense against any alleged infringement of letters patent, copyright, or trademark, or as a defense against any liability for such infringement.

Comments, criticisms, and suggestions are invited, and should be forwarded to the American Society for Metals, Metals Park, Ohio 44073.

Library of Congress Catalog Card Number: 86-72113
ISBN: 0-87170-226-6
SAN 204-7586

Editorial and production coordination by Carnes Publication Services, Inc.

PRINTED IN THE UNITED STATES OF AMERICA

Mechanical Properties of Aramid, Polyamide, Polyester, and Nylon Fibers

Fiber	Density Mg/m³	Density lb/in.³	Tensile strength MPa	Tensile strength ksi	Tensile modulus GPa	Tensile modulus 10^6 psi	Ultimate elongation, %
Aramid-Kevlar 29	1.44	0.052	3620	525	83	12	4.4
Aramid-Kevlar 49	1.44	0.052	3620	525	124	18	2.9
Polyamide	1.13	0.041	830	120	2.8	0.4	...
Polyester-Dacron Type 68	1.38	0.050	1120	162	4.1	0.6	14.5
Nylon–Du Pont 728*	1.13	0.041	990	143	5.5	0.8	18.3
Spectra-900	0.97	0.035	2590	375	117	17	...

*Unimpregnated twisted yarn test–ASTM D2250.

Effect of Tension-Tension Fatigue on Aramid (Kevlar 29) Fibers (Du Pont Co.)

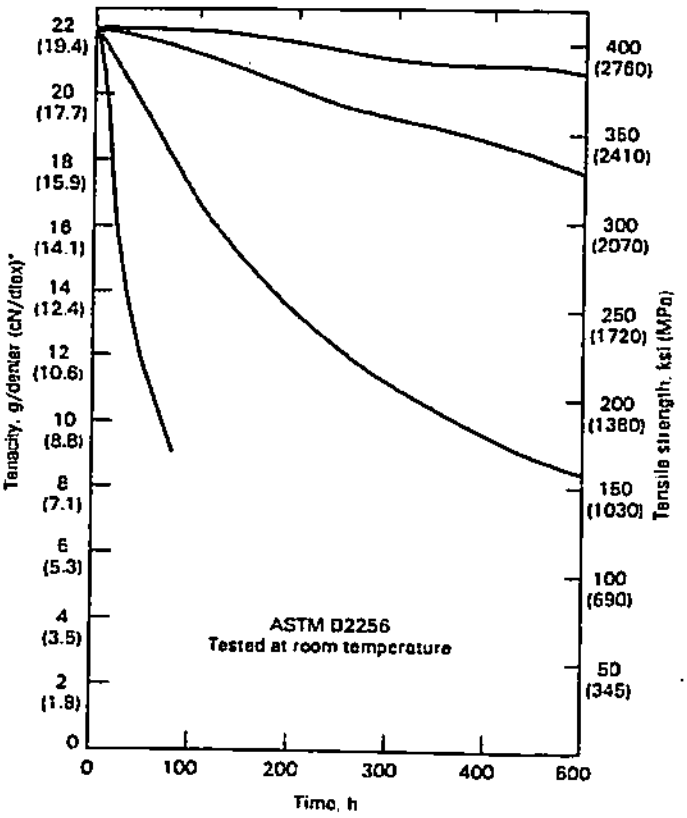
Cycled between (% of ultimate tensile strength) High	Low	No. of cycles	Break load after cycling N	Break load after cycling lb	Decrease in tensile strength due to fatigue
Control		...	552	124	...
74	45	1000	578	130	None
52	29	1000	610	137	None
31	8	1000	587	132	None
10	0	13×10^6	525	118	5%

1500 denier [1670 dtex] 2-ply yarn of Kevlar 29 was tested using air-actuated 4-D cord clamps on an Instron test machine, at 254 mm (10 in.) original gage length, 10% per minute elongation, 55% R.H., and 22 °C (72 °F).

Coating Materials Used Successfully With Kevlar 29 Aramid Fiber (Du Pont)

Coating	Typical end uses
Neoprene synthetic rubber	Inflatable boats
Hypalon synthetic rubber	Pond liners, tarpaulins
Nitrile rubber	Pressure diaphragms
Nordel hydrocarbon rubber	Heat-resistant conveyor belts
Buna-N	Hoses
Urethane polymers	Inflatable structures
Silicon and fluorosilicon	Belting
Polyvinyl chloride	Air-supported structures
Teflon [TFE, FEP] fluorocarbon resin	Nonstick belts
Polyvinyl alcohol	Specialty uses
Laminations: Tedlar polyvinyl fluoride / Mylar polyester	Lighter-than-air craft

Effect of Temperature on Tensile Strength of Aramid (Kevlar 29) Fiber (Du Pont Co.)



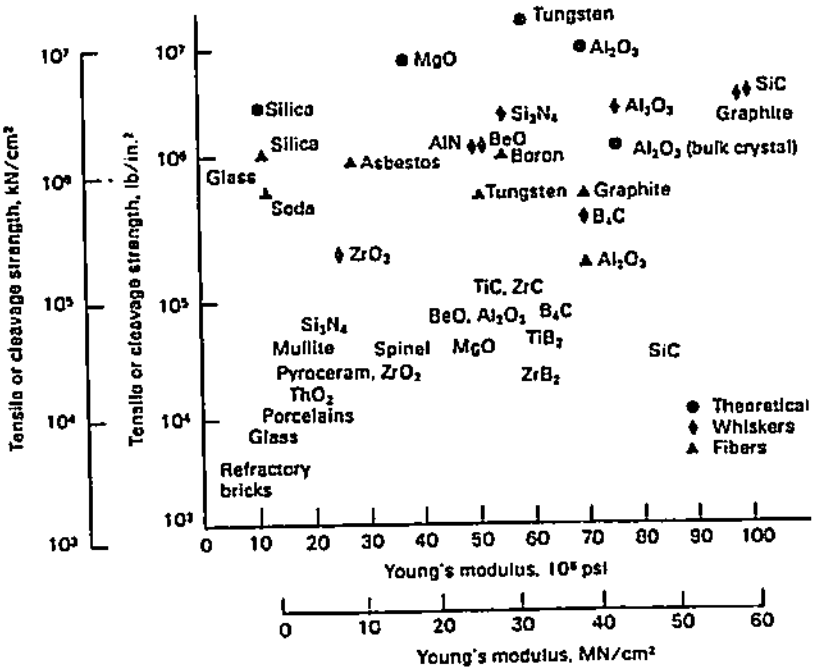
*Conversion factor: $\frac{\text{lb}}{\text{in}^2} = \left(\frac{\text{g}}{\text{denier}}\right) \times \text{density}\left(\frac{\text{g}}{\text{cm}^3}\right) \times 12\,800$

Chemical Resistance of Kevlar (Ref 34)

Chemical	Concentration, %	Temperature °C	Temperature °F	Time, h	Strength loss, % Kevlar 29	Strength loss, % Kevlar 49
Hydrochloric acid	37	21	70	100	72	63
Hydrochloric acid	37	21	70	1000	88	81
Hydrofluoric acid	10	21	70	100	10	6
Nitric acid	1	21	70	100	16	5
Nitric acid	10	21	70	100	79	77
Sulfuric acid	10	21	70	100	9	12
Sulfuric acid	10	21	70	1000	59	31
Sodium hydroxide	10	21	70	1000	74	53
Ammonium hydroxide	28	21	70	1000	9	7
Acetone	100	21	70	1000	3	1

(continued)

Strength Vs. Modulus for Tungsten and Various Ceramics in Bulk, Fiber, and Whisker Forms (Ref 8, p 359)

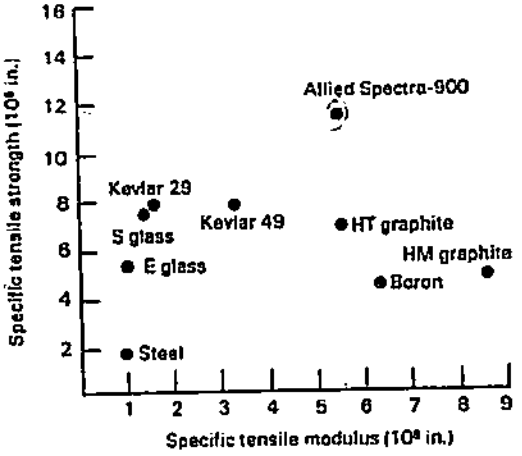


Comparative Mechanical Properties of Kevlar, Glass, and Graphite Fibers (Du Pont Co.)

Property	Kevlar 29	E glass	Graphite
Tensile strength*:			
MPa	3620	3415	2760
ksi	525	350	400
Tensile modulus*:			
GPa	82.7	68.9	220
10^6 psi	12	10	32
Density:			
g/cm³	1.44	2.52	1.74
lb/in.³	0.052	0.091	0.063
Brittleness	Tough	Brittle	Brittle
Abrasiveness	No	Yes	Yes

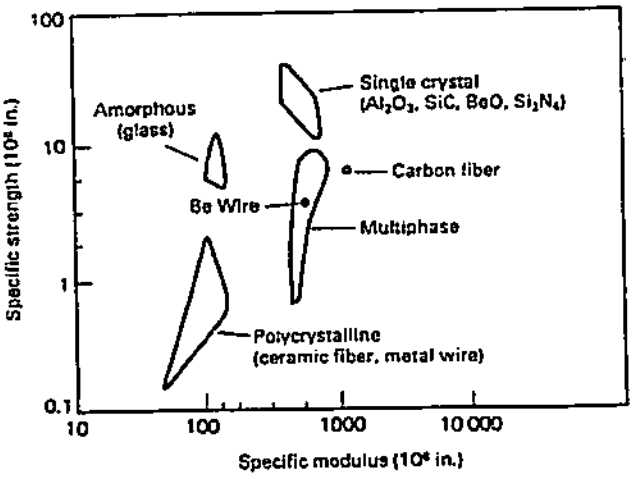
*Resin-impregnated strand test.

Specific Strength Vs. Specific Modulus for Reinforcing Fibers (Allied Fibers)



Room-Temperature Specific Strength and Specific Stiffness of Several Fibers (Ref 11, p 25)

Specific values in this figure were determined by dividing strength or modulus by density, expressed in lb/in.³ or kg/M³.



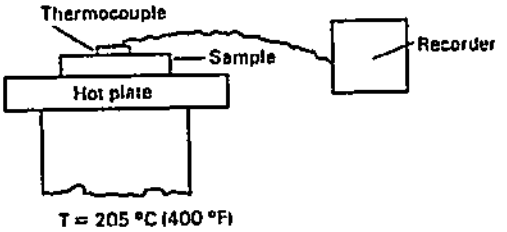
Characteristics of Carbon-Boron Alloy Fiber Groups (Ref 73)

Characteristic	Group A	Group B	Group C	Group D
Carbon interlayer	No	No	Yes	Yes
Number of CVD reaction chambers	4	3	3	3
Boron content*, wt %	43–46	35–39	46–48	48–51

*Unpublished research, D. L. McDanels, NASA Lewis Research Center.

Thermal Conductivity of Kevlar Felts and Fabrics Vs. Other Materials (Du Pont Co.)

Fabric	Weight g/m²	Weight oz/yd²	Thickness mm	Thickness mils	Lag time, s	Thermal conductivity, cal/cm²·s·°C	Temperature rise in 25 s °C	Temperature rise in 25 s °F
Kevlar 29 (1 ply)	333	9.8	0.76	30	0	0.324	60	108
Kevlar 29 (3 ply)	998	29.4	2.16	85	3	0.162	30	54
Kevlar 29 (felt)	917	27.0	2.67	105	1.5	0.084	16	28
Fiberglass (1 ply)	285	8.4	0.30	12	0	0.600	111	200
Fiberglass (8 ply)	2282	67.2	2.16	85	5.1	0.105	19	35
Asbestos	1386	40.8	2.29	90	2.5	0.168	31	55



Schematic of Test Apparatus for Determining Lag Time

Lag time is time between placing sample in contact with hot plate and any perceptible recorder readout.

Some Typical Fabric Dimensions (Hexcel-Trevarno)

Construction	Weave	Thickness, mils	Width, in.	Weight, oz/yd²
Graphite				
12.5 × 12.5	Plain	7.2	42	5.7
24.0 × 24.0	Satin	13.5	42	10.0
10.5 × 10.5	Plain	6.0	42	5.5
16.0 × 24.0	Plain	6.1	38	4.7
Kevlar				
34 × 34	Plain	4.5	38	1.8
50 × 50	Satin	11	38	5.0
22 × 22	Plain	4.5	38	2.2
17 × 17	Plain	10	38, 50	5.0
17 × 17	Crowfoot	10	38, 50	5.0
13 × 13	Plain	10	50	5.0
16 × 16	Satin	13	50	9.0
28 × 28	Basket	20	50	10.5
26 × 22	Basket	20	44, 50, 60	13.5
17 × 30	Plain	7	38	3.1
S Glass				
24 × 22	Plain	5.5	38	3.7
18 × 18	Plain	9	38	5.8
48 × 30	Crowfoot	9	30	8.8
57 × 30	Crowfoot	5.5	38	5.4
57 × 54	Satin	8.5	38	8.9
Ceramic				
48 × 47	Satin	9.0	38	7.5

Comparative Textile Fiber Properties (Ref 90)

	Spectra 900	Spectra 1000	Aramid LM	Aramid HM	Carbon HT	Carbon HM
Denier/Number of filaments	1200/118	650/120	1500/1000	1500/1000	1730/3000	1630/3000
Tenacity, g/d	30	35	22	22	20	14
Elongation, %	3.5	2.7	3.6	2.8	1.2	0.6
Tensile modulus, g/d	1400	2000	488	976	1500	2400
Shrinkage at boil, %	<1	<1				
Specific gravity	0.97	0.97	1.44	1.44	1.73	1.81
Melting point, °C	147	147				
Filament size, μm	38	27	12	12	7.0	6.5

Additives, Report NASA TN D-2757, NASA, Cleveland, Ohio, April 1965

84. C. A. Hoffman and J. W. Weeton, *Metal-Metal Laminar Composites for High Temperature Applications*, Report NASA TM X-68056, NASA, Cleveland, Ohio, May 1972

85. C. A. Hoffman and J. W. Weeton, *Tensile Behavior of Unnotched and Notched Tungsten-Copper Laminar Composites*, Report NASA TN D-8254, NASA, Cleveland, Ohio, 1976

86. E. J. Peters, and Dr. Paul Boymal, "Ceramic Fibers in Advanced Composites," Fiber Development Conference, Impact 1985, Sponsored by Marketing Technology Service, Inc., Fort Lauderdale, Florida, March 10–12, 1985

87. "Developmental Data, Fiberfrax Reinforcement of Plastics," Technical Bulletin, Sohio Engineered Materials Co., Fibers Division, Sohio Carborundum, Niagara, New York

88. J. W. Weeton and R. A. Signorelli, "Fiber-Metal Composites," *Strengthening Mechanisms-Metals and Ceramics*, edited by John J. Burke, Norman L. Reed, and Volker Weiss, Syracuse University Press, Syracuse, New York, 1966

89. John A. Alexander, Robert G. Shaver, and James C. Withers, *Critical Analysis of Accumulated Experimental Data on Filament-Reinforced Metal-Matrix Composites*, Contract No. NASW-1779, NASA, June 1969

90. "New Technology, New Horizons," Technical Bulletin, Alcoa Fibers Division, New York, 1985

91. Donald W. Petrasek, *High-Temperature Strength of Refractory-Metal Wires and Consideration for Composite Applications*, Report NASA TN D-6881, NASA, Cleveland, Ohio, August 1972

92. Donald W. Petrasek and Robert A. Signorelli, *Tungsten Fiber Reinforced Superalloys—A Status Review*, Report NASA TM-82590, NASA, Cleveland, Ohio, January 1981

93. *Carbon 76*, Conference proceedings of the Second International Carbon Conference, sponsored by the Working Group on Carbon of the German Ceramic Society, Baden-Baden, West Germany, 1976

94. Erich Fitzer, Antonios Gkogkidis, and Michael Heine, "Carbon Fibres and Their Composites," *High Temperatures—High Pressures*, Vol 16, 1984

95. C. T. Lynch, and J. P. Kershaw, *Metal Matrix Composites*, The Chemical Rubber Co., CRC Press, Cleveland, Ohio, 1972

96. *Plastics Engineering*, SAE, November 1985

97. *Plastics Compounding*, Harcourt Brace Jovanovich Publications, November/December 1985

98. *Material Engineering*, Penton/IPC, August 1978

99. *Modern Plastics Encyclopedia*, McGraw-Hill, 1978–1979

100. Rod Doerr, Ed Green, B. Lyon and S. Taha, *Development of Effective Machining and Tooling Techniques for Kevlar Composite Laminates*, Applied Technology Laboratories, U.S. Army Research & Technology Laboratories (AVRADCOM), June 1982

101. Anon, *A Guide to Cutting and Machining Kevlar Aramid Composites*, Du Pont Company, 1983

102. *Materials Review for '72*, SAMPE Vol. 17, Proceedings of National SAMPE Symposium and Exhibition, Los Angeles, California, April 11–13, 1972, SAMPE, Azusa, California, 1972

103. Leonard E. Samuels, *Metallographic Polishing by Mechanical Methods*, American Society for Metals, Metals Park, Ohio, 1982

104. S. R. Levitt, "High Strength Graphite Fibre/Lithium Aluminosilicate Composites," *Journal of Materials Science*, Vol 8, 1973

105. R. L. Mehan, "Effect of SiC Content and Orientation on the Properties of Si/SiC Ceramic Composites," *Journal of Materials Science*, Vol 13, 1978

106. J. Sambell, D. H. Bowen, and D. C. Phillips, "Carbon Fiber Composites with Ceramic Glass Matrices," *Journal of Materials Science*, Vol 7, 1972

107. I. W. Donald and P. W. McMillan, "Review Ceramic Matrix Composites," *Journal of Materials Science*, Vol 11, 1976

108. *Treatise on Material Science and Technology*, Vol 11, edited by R. K. MacCrone, Academic Press, Orlando, Florida, 1977

109. F. J. Jelinek, "Ceramic Composites," *Current Awareness Bulletin*, Metals and Ceramics Information Center, Columbus, Ohio, December 1985, Issue No. 154

110. *Composite Materials*, edited by L. J. Broutman and R. H. Krock, Vol. 1, *Interfaces in Metal Matrix Composites*, edited by Arthur G. Metcalfe, Academic Press, New York, 1974

111. B. I. Edelson and W. M. Baldwin, Jr., *The Effect of Second Phases on the Mechanical Properties of Alloys*, Transactions of the American Society for Metals, Volume LV, March, June, September, December, 1962, American Society for Metals, Metals Park, Ohio, 1962

112. G. E. Metzger, "Joining of Metal-Matrix Fiber-Reinforced Composite Materials," *WRC Bulletin No. 207*, Welding Research Council, 1975

113. R. L. Mehan, R. P. Jakas, and G. A. Bruch, "*Behavior Study of Sapphire Wool Aluminum Composites*," AFML-TR-68-100, May 1968, Space Sciences Laboratory, General Electric Company, Air Force Contract No. F 33615-67-C-1308

114. A. W. H. Morris and A. Burwood-Smith, "Some Properties of a Fiber-Reinforced Nickel-Base Alloy," *Fibre Science Technology*, 3(1), 1970, pp 53–78

115. R. H. Baskey, *Fiber Reinforced Metallic Composite Materials*, Clevite Corporation (AFML-TR-67-196 AD-825364), September 1967

116. N. Nilsen and J. H. Sovik, "Fatigue of Tungsten Fiber Reinforced Nickel," *Practical Metallic Composites*, Proceedings of the Spring Meeting, Institution of Metallurgists, London, 1974, pp B51–B54

117. Diane M. Essock, "FeCrAlY Matrix Composites for Gas Turbine Applications," *Advanced Fibers and Composites for Elevated Temperatures*, edited by I. Ahmad and B. R. Noton, Proceedings of the 108th AIME Annual Meeting and Symposium, sponsored by the Metallurgical Society of AIME and ASM Joint Composite Materials Committee, New Orleans, Louisiana, February 20–21, 1979, The Society of AIME, Warrendale, Pennsylvania, 1980

118. R. W. Jech and R. A. Signorelli, *Evaluation of Silicon Carbide Fiber/Titanium Composites*, TM-79232, NASA Lewis Research Center, Cleveland, Ohio, July 1979

119. I. J. Toth, W. D. Brentnall, and G. D. Menke, "Making a Product from Composites," *Journal of Metals*, Vol. 24, October 1972, Metallurgical Society/AIME

120. D. Cratchley, "Factors Affecting the UTS of a Metal/Metal-Fibre Reinforced System," *Powder Metallurgy*, No. 11, 1963

121. K. M. Prewo and K. G. Kreider, "High-Strength Boron and Borsic Fiber Reinforced Aluminum Composites," *Journal of Composite Materials*, July 1972

122. G. V. Samsonov, A. D. Panasyk and H. S. Borivtkova, "Wettability and Surface Properties of Melts and Solid Bodies," Naukova Dumka, Kiev, 1972

123. V. I. Tumanov, A. E. Goyburov and G. M. Kondratenko, ibid.

124. J. Theberge et al., 30th Annual Conference, Reinforced Plastics/Composites Institute, SPI, 1972; Section 14-C

125. K. M. Prewo, "New Dimensionally and Thermally Stable Composite," Conference on Advanced Composites, Technology Conference Associates, El Segundo, CA, December 1979, p. 1

EXHIBIT C

JOURNAL OF APPLIED POLYMER SCIENCE VOL. 18, PP. 2539-2568 (1974)

Interaction of Melt Spinning and Drawing Variables on the Crystalline Morphology and Mechanical Properties of High-Density and Low-Density Polyethylene Fiber

JAMES L. WHITE, KHUSHAL C. DHAROD, and EDWARD S. CLARK, *Department of Chemical and Metallurgical Engineering, The University of Tennessee, Knoxville, Tennessee 37916*

Synopsis

An experimental study of the spinnability and the variation in crystallinity and orientation in high-density and low-density polyethylene fibers with melt spinning and drawing conditions has been carried out. Three polymers (two high-density and one low-density) and eicosane ($C_{20}H_{42}$) were studied. The maximum spinnability was in the lower molecular weight high-density polyethylene. Hermans-Stein a, b, and c crystallographic axis orientation factors were computed from wide-angle x-ray scattering patterns. In the spun fiber, small take-up velocities cause the b axis to become perpendicular to the fiber axis in each fiber. The c axis increasingly orients itself parallel to the fiber axis as take-up velocity increases. The a axis orientation is different for each polymer. The results are interpreted in terms of modern theories of crystalline morphology, specifically the development of row structures. In the drawing experiments, the two high-density polyethylenes necked. A phenomenological theory of necking is discussed. The a, b, and c axis orientation factors were determined for different stages of drawing. In the necked regions and in completely drawn fibers, the c axis was parallel to the fiber axis and the a and b axes are perpendicular to the fiber axis. The tangent Young's modulus and tensile strength of the spun fibers increased with take-up velocity and in the drawn fibers were an order of magnitude higher than in the spun fiber. The mechanical properties of spun fiber may be correlated with the c axis (Hermans) orientation factor. The drawn fiber shows significant variations in Young's modulus and tensile strength at constant unit cell orientation.

INTRODUCTION

The production of fibers from polymer melts generally involves two steps. First, melt is extruded producing a vertical descending thread which is cooled in transit and taken up on a godet in solidified form. This process is known as *melt spinning*. The spun fiber is then subjected to a second operation in which it is unwound from a slow roll, stretched (drawn) under controlled temperature conditions, and taken up on a fast roll. This second process is known as *drawing*. A wide range of spinning and drawing variables is available to the fiber manufacturer. The choice is one not to be taken lightly or completely on the basis of economic considerations for the

DFM
8/11/06

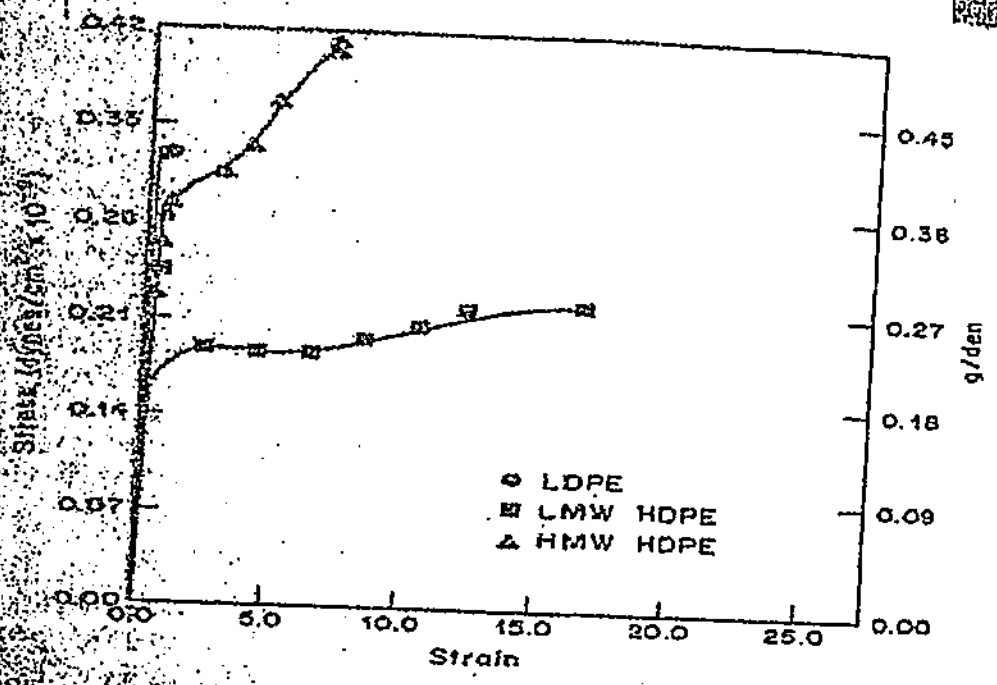
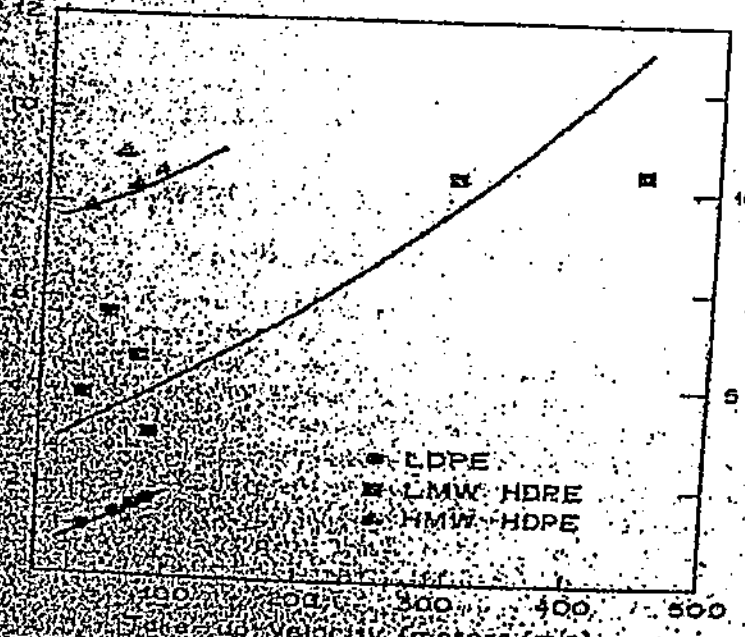


Fig. 11. Stress–strain curves for three different polyethylene fibers spun under the same conditions.



...polyethylene fibers as a function of take-up velocity.

DPM
8/11/06

EXHIBIT D

(2)

The UHMWPE Handbook

Ultra-High Molecular Weight Polyethylene in Total Joint Replacement

Steven M. Kurtz, Ph.D.
Principal Engineer, Exponent, Inc.
Research Associate Professor, Drexel University
3401 Market Street, Suite 300
Philadelphia, PA 19104

ELSEVIER
ACADEMIC PRESS

AMSTERDAM • BOSTON • HEIDELBERG • LONDON
NEW YORK • OXFORD • PARIS • SAN DIEGO
SAN FRANCISCO • SINGAPORE • SYDNEY • TOKYO

Contributors

Jörgen Bergström Ph.D.
Senior Engineer
Exponent, Inc.
21 Strathmore Rd.
Natick, MA 01760

Pierangiola Bracco
Researcher
Dipartimento di Chimica IFM
Università di Torino
Via Giuria 7
10125 Torino (Italy)

Luigi Costa Ph.D.
Professor
Dipartimento di Chimica IFM
Università di Torino
Via Giuria 7
10125 Torino (Italy)

Peter Cripton Ph.D.
Assistant Professor
Department of Mechanical Engineering
University of British Columbia
2054-2324 Main Mall
Vancouver, B.C.
V6T1Z4 Canada

Avram Allan Edidin Ph.D.
Research Associate Professor
School of Biomedical Engineering, Science, and Health Systems
Drexel University
3141 Chestnut St.
Philadelphia, PA 19104

Stefan Gabriel Ph.D., P.E.
Principal Engineer
Smith & Nephew Endoscopy
130 Forbes Blvd.
Mansfield, MA 02048

Stephen Spiegelberg Ph.D.
President
Cambridge Polymer Group, Inc.
52-R Roland St.
Boston, MA 02129

Marta Villarraga Ph.D.
Managing Engineer, Exponent, Inc.
Research Associate Professor
School of Biomedical Engineering, Science, and Health Systems
Drexel University
3401 Market St., Suite 300
Philadelphia, PA 19104

the elemental building blocks are individual metal atoms (e.g., Co, Cr, Mo) or relatively small molecules (e.g., metal carbides or oxides). However, in a polymer, the molecular size can comprise more than a 100,000 monomer units, with molecular weights of up to millions of g/mol.

The molecular chain architecture of a polymer also imparts many unique attributes, including temperature dependence and rate dependence. Some of these unique properties are further illustrated in the specific case of UHMWPE in subsequent sections of this chapter. For further background on general polymer concepts, the reader is referred to textbooks by Rodriguez (1989) and Young (1983).

What Is Polyethylene?

Polyethylene is a polymer formed from ethylene (C_2H_4), which is a gas having a molecular weight of 28. The generic chemical formula for polyethylene is $-(C_2H_4)_n-$, where n is the degree of polymerization. A schematic of the chemical structures for ethylene and polyethylene is shown in Figure 1.4.

For UHMWPE, the molecular chain can consist of as many as 200,000 ethylene repeat units. Put another way, the molecular chain of UHMWPE contains up to 400,000 carbon atoms.

There are several kinds of polyethylene (LDPE, LLDPE, HDPE, UHMWPE), which are synthesized with different molecular weights and chain architectures. LDPE and LLDPE refer to low-density polyethylene and linear low-density polyethylene, respectively. These polyethylenes generally have branched and linear chain architectures, respectively, each with a molecular weight of typically less than 50,000 g/mol.

HDPE is a linear polymer with a molecular weight of up to 200,000 g/mol. UHMWPE, in comparison, has a viscosity average molecular weight of up to 6 million g/mol. In fact, the molecular weight is so ultra-high that it cannot be measured directly by conventional means and must instead be inferred by its intrinsic viscosity (IV).

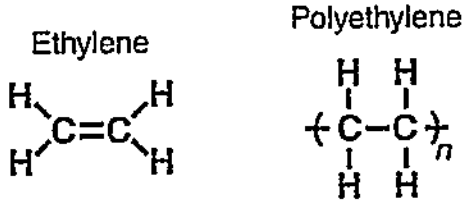


Figure 1.4
Schematic of the chemical structures of ethylene and polyethylene.

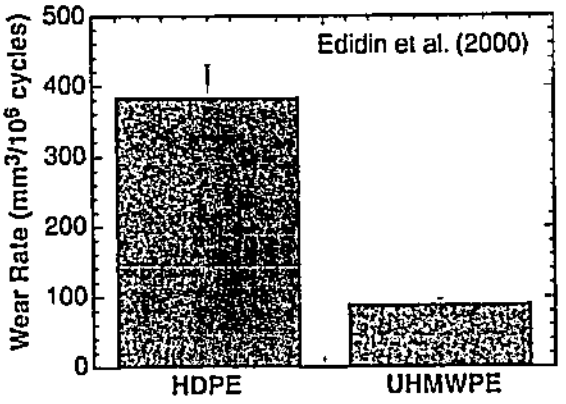


Figure 1.5
Comparison of wear rates of HDPE and UHMWPE in a multidirectional hip simulator. (From Edidin A.A., and S.M. Kurtz. 2000. The influence of mechanical behavior on the wear of four clinically relevant polymeric biomaterials in a hip simulator. *J Arthroplasty* 15:321–331.)

Crystallinity

One can visualize the molecular chain of UHMWPE as a tangled string of spaghetti, more than a kilometer long. Because the chain is not static, but imbued with internal (thermal) energy, the molecular chain can become mobile at elevated temperatures. When cooled below the melt temperature, the molecular chain of polyethylene has the tendency to rotate about the C–C bonds and create chain folds. This chain folding, in turn, enables the molecule to form local ordered, sheetlike regions known as crystalline lamellae. These lamellae are embedded within amorphous (disordered) regions and may communicate with surrounding lamellae by tie molecules. All of these morphological features of UHMWPE are shown schematically in Figure 1.6.

The degree and orientation of crystalline regions within a polyethylene depends on a variety of factors, including its molecular weight, processing conditions, and environmental conditions (such as loading), and will be discussed in later chapters.

The crystalline lamellae are microscopic and invisible to the naked eye. The lamellae diffract visible light, giving UHMWPE a white, opaque appearance at room temperature. At temperatures above the melt temperature of the lamellae, approximately 137°C, UHMWPE becomes translucent. The lamellae are on the order of 10–50 nm in thickness and 10–50 μm in length (Kurtz et al. 1999). The average spacing between lamellae is on the order of 50 nm (Bellare, Schnablegger, and Cohen 1995).

The crystalline morphology of UHMWPE can be visualized using transmission electron microscopy (TEM), which can magnify the polymer by up to

summarizes the clinical performance of UHMWPE hip implants and discusses the patterns of wear and surface damage that occur during implantation. Chapter 6 describes alternatives to conventional UHMWPE in hip replacement. Chapters 7 and 8 relate to the development and clinical performance of UHMWPE in knee replacement. Chapter 9 is devoted to clinical applications of UHMWPE in the shoulder, and Chapter 10 covers the use of UHMWPE in the spine.

The topics outlined in this *Handbook* may be used as a resource in undergraduate, as well as graduate, courses in biomaterials and orthopedic biomechanics. Students in these disciplines can learn a great deal from exposure to the historical development of total joint replacements within the context of UHMWPE. The first two main sections of this book, which cover the fundamentals of UHMWPE and clinical applications in the spine and upper and lower extremities, are intended as a resource for undergraduate instruction.

The third section of this book, which covers more specialized topics related to UHMWPE, is intended for an audience of graduate students and orthopedic researchers. Chapter 11 covers the chemistry of UHMWPE following irradiation, which leads to oxidation and crosslinking of the material. Chapter 12 describes the characterization methods for UHMWPE in the context of regulatory submissions prior to clinical trials. In Chapter 13, we review the development of the small punch test, a miniature specimen mechanical testing technique that has recently been standardized. Chapter 14 describes the micromechanical modeling of conventional and highly crosslinked UHMWPE. The final chapter in this work, Chapter 15, is a compendium of the processing, packaging, and sterilization information for highly crosslinked and thermally treated UHMWPE materials that are currently used in hip and knee arthroplasty.

Understanding basic chemical structure and morphology is an important starting point for appreciating the unique and outstanding properties of UHMWPE. The chapters that follow and describe the processing, as well as the sterilization, of UHMWPE will continue to build on the conceptual foundation established in this introduction.

References

Bellare A., H. Schnablegger, and R.E. Cohen. 1995. A small-angle x-ray scattering study of high-density polyethylene and ultra-high molecular weight polyethylene. *Macromolecules* 17:2325–2333.

Charnley J. 1963. Tissue reaction to the polytetrafluoromethylene. *Lancet* II:1379.

Charnley J. 1979. Low friction principle. In *Low friction arthroplasty of the hip: Theory and practice*. Berlin: Springer-Verlag.

Chubberley A.H. 1965. Ultra-high molecular weight polyethylenes. In *Modern plastics encyclopaedia*. New York: McGraw-Hill.

Edidin A.A., and S.M. Kurtz. 2000. The influence of mechanical behavior on the wear of four clinically relevant polymeric biomaterials in a hip simulator. *J Arthroplasty* 15:321–331.

Kurtz S.M., O.K. Muratoglu, M. Evans, A.A. Edidin. 1999. Advances in the processing, sterilization, and crosslinking of ultra-high molecular weight polyethylene for total joint arthroplasty. *Biomaterials* 20:1659–1688.

Rodriguez F. 1989. *Principles of polymer systems*. New York: Hemisphere.

Wroblewski B.M., P.D. Siney, D. Dowson, and S.N. Collins. 1996. Prospective clinical and joint simulator studies of a new total hip arthroplasty using alumina ceramic heads and cross-linked polyethylene cups. *Journal of Bone & Joint Surgery* 78B:280–285.

Young R.J. 1983. *Introduction to polymers*. London: Chapman and Hall.

Chapter 1. Reading Comprehension Questions

1.1. Let A, B, and C be monomers. What is the molecular structure of a linear homopolymer?
- a) -A-A-B-A-A-B-A-A-B-
- b) -A-B-C-A-B-C-A-B-C-
- c) -B-C-C-C-C-C-C-C-C-
- d) -B-B-B-B-B-B-B-B-B-
- e) -C-A-A-C-A-A-C-A-A-

1.2. Which of the following polymers is NOT synthesized from ethylene?
- a) LLDPE
- b) PTFE
- c) UHMWPE
- d) HDPE
- e) LDPE

1.3. What is the major difference between HDPE from UHMWPE?
- a) Molecular weight
- b) Monomer
- c) Chemical composition
- d) Color
- e) All of the above

1.4. What are the crystals in polyethylene made up of?
- a) Folded molecular chains
- b) Calcium stearate
- c) Aluminum tetrachloride
- d) Copolymer
- e) Branched chain ends

1.5. UHMWPE exhibits which of the following transition temperatures?
- a) Glass transition
- b) Melting transition
- c) Flow transition
- d) Glass and melting transitions
- e) Glass, melting, and flow transitions

EXHIBIT E

Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA

Document issued on: August 30, 2002

This document supersedes 510(k) Sterility Review Guidance K90-1, dated November 16, 2001.

U.S. Department Of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Timothy A. Ulatowski at (301) 443-8879 or by email tau@cdrh.fda.gov.

Additional Copies

Additional copies are available from the Internet at: http://www.fda.gov/cdrh/ode/guidance/361.pdf, or CDRH Facts-On-Demand. In order to receive this document via your fax machine, call the CDRH Facts-On-Demand system at 800-899-0381 or 301-827-0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt, press 1 to order a document. Enter the document number (361) followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Updated 510(k) Sterility Review Guidance K90-1; Guidance for Industry and FDA

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

I. Background

On November 16, 2001, the Office of Device Evaluation released updated review procedures regarding sterilization data submitted in premarket notification (510(k)) submissions as outlined in Blue Book Memorandum #K90-1, issued on February 12, 1990. The issuance of the November memorandum was deemed necessary given several significant changes that had occurred in the regulatory environment that had made aspects of the February 1990 memorandum obsolete. Specifically, these included:

1. Promulgation of the Quality System regulation (QS regulation, 21 CFR 820) in 1996;

2. Issuance of Blue Book Memorandum #K97-1 regarding changes to existing devices that can be made without submitting a new 510(k); and

3. Enactment of the Food and Drug Administration (FDA) Modernization Act of 1997 (FDAMA), which among many things, separated compliance with QS requirements from the substantial equivalence decision in most cases.

In 1997, the Center for Devices and Radiological Health (CDRH) decided that, given a manufacturer's obligation to comply with the QS requirements, the safety and effectiveness of a device manufacturer's sterilization process would best be ensured through compliance with the QS regulation rather than through 510(k) review. This decision was communicated to ODE staff and the medical device industry in Blue Book Memorandum #K97-1 entitled, "Deciding When to Submit a 510(k) for a Change to an Existing Device."[1] In this guidance, CDRH stated that manufacturers may modify existing devices in a number of ways, including labeling changes, technology or performance specification changes, and materials changes without submitting a new

[1] This guidance is available on CDRH's website at: http://www.fda.gov/cdrh/ode/510kmod.html

510(k) unless 'a change or the sum of the incremental changes exceeds the section 807.81(a)(3) threshold, "could significantly affect the safety or effectiveness of the device.'" CDRH included changes in the sterilization method as a type of change that would not normally trip the regulatory threshold for submission of a new 510(k). As stated in the guidance, changes in sterilization processes do not require 510(k) clearance, unless the changes significantly alter the properties/specifications of a device or result in a lower sterility assurance level (SAL). In instances where a manufacturer concludes that a change in sterilization method has not significantly affected device properties/specifications or resulted in a lower SAL, no 510(k) need be submitted. Rather, the appropriate documentation must be maintained at the manufacturing site in accordance with the QS regulation requirements.

The enactment of FDAMA emphasized the separation between issues of compliance with the QS regulation and determinations of substantial equivalence (SE). In a new statutory provision, the agency was instructed not to withhold a determination of the initial classification of a device because of a failure to comply with any statutory provision unrelated to the SE decision unless "there is a substantial likelihood that the failure to comply with such regulations will potentially present a serious risk to human health." This new provision, Section 513(f)(5) of the Federal Food, Drug, and Cosmetic Act, specifically includes noncompliance with good manufacturing practices (now referred to as QS requirements) as a failure that should not ordinarily delay an SE decision. These events prompted FDA to revise its procedures for the review of sterilization information in all 510(k) submissions in 1997 and to issue the November 2001 memorandum.

In recent discussions with Center staff, it was determined that additional guidance on non-traditional methods of sterilization is needed. While the agency has experience with some types of non-traditional methods of sterilization, FDA recognizes that there may be unique or novel sterilants that have not yet been submitted in a premarket notification or that have not yet been successfully implemented by device manufacturers. Given this variety in non-traditional methods, CDRH decided that additional guidance is needed to help review staff differentiate between various types of non-traditional methods of sterilization and how applications in which they are employed should be handled.

II. Methods of Sterilization

FDA considers there to be two categories of sterilization methods used to sterilize medical devices - traditional and non-traditional. Specific methods for each category are listed below.

A. Traditional Methods of Sterilization

Traditional methods of sterilization include:

- Dry heat sterilization
- Moist heat sterilization

- Ethylene Oxide (EO) with devices placed in a fixed chamber
- Radiation (gamma and electron beam)
- Liquid chemical sterilants for sterilizing single-use devices incorporating materials of animal origin

B. Non-Traditional Methods of Sterilization

In general, methods of sterilization outside the scope of specific CDRH-recognized standards are non-traditional. A new method of sterilization remains a non-traditional method unless and until: a) the specific sterilization method is incorporated into a new or existing voluntary consensus standard formally recognized by the Agency or b) CDRH evaluates the validation data for the method of sterilization as part of a quality system evaluation and finds it satisfactory for specified types of devices.

1. As of the date of this memorandum, non-traditional methods of sterilization include:

   - EO not using a fixed chamber, e.g., EO injection into a porous polymer bag. Terms used for this process include:

     - "bag method"
     - "diffusion method"
     - "sterilization pouch"
     - "injection method"
     - "validation parts 'A' and 'B'"

   Less common indications of this type of sterilization are:

     - a long gas dwell time (>8 hours) or the absence of a specified gas dwell time
     - use of EO volume (e.g., 7.2 grains) instead of concentration (e.g., 500 – 600 mg/l)
     - mention of EO (or gas) cartridge
     - use of humidichips
     - use of "100% EO in-house"

- High intensity light
- Chlorine dioxide
- Ultraviolet light
- Combined vapor and gas plasma
- Vapor systems (e.g., peroxide or peracetic acid)
- Filtration methods
- Limited use of a liquid peracetic acid system in endoscopy and with metal instruments

2. In addition to the above non-traditional sterilization methods, ODE reviewers are occasionally presented with non-traditional methods employing a unique or novel sterilant that the agency has not previously seen in a premarket submission, for which there is no related inspectional history, or for which there is little or no published literature discussing its safety and effectiveness for its intended use. Such methods include, but are not limited to, the use of microwave radiation, pulsed light, gas plasma, and sound waves. Given that the agency has had little or no experience with these methods for achieving sterilization and is concerned about a manufacturer's ability to successfully use such methods without adversely affecting the SAL, reviewers should follow the additional procedures identified below in Section IV when reviewing a 510(k) in which a sterilization method of this type is employed.

III. Review Procedures for All Sterilization Methods

Regardless of the method of sterilization, ODE scientific reviewers should gather and review the following sterilization information for all 510(k)s for devices labeled as sterile:

- The sterilization method that will be used (e.g., dry heat, moist heat,E O, radiation);
- A description of the method that will be used to validate the sterilization cycle, but not the validation data itself;
- A description of the packaging to maintain the device's sterility, not including package integrity testing data;
- If sterilization involves EO, the maximum levels of residuals of EO and ethylene chlorhydrin that remain on the device (note: the ethylene glycol

residual level was dropped from this updated guidance because the recognized standard, "ANSI/AAMI/ISO 10993-7:1995 Biological Evaluation of Medical Devices – Part 7: Ethylene Oxide sterilization residuals," does not include measurement of ethylene glycol residuals);

- If the product is labeled "pyrogen free," a description of the method used to make the determination, e.g., limulus amebocyte lysate (LAL);
- The SAL (e.g., 10^{-6} for all devices, except 10^{-3} for devices only contacting intact skin); and
- In the case of radiation sterilization, the radiation dose.

IV. Additional Procedures for 510(k)s Citing Non-Traditional Sterilization Methods

As delineated in Blue Book #K97-1, a manufacturer's change in the sterilization method for an existing device will generally not require the submission of a new 510(k). Similarly, a manufacturer's use of a non-traditional sterilization method should not ordinarily effect or delay a substantial equivalence determination. In assessing the impact of a sterilization method on a device, the manufacturer should ensure that the performance characteristics have not been compromised and that the SAL remains 10^{-6} (10^{-3}, as appropriate). For 510(k)s citing a non-traditional method of sterilization, scientific reviewers should notify their Branch Chief of the pending submission and proceed as described below. Situations involving non-traditional sterilization methods should be brought to the attention of the Assistant to the Director, Office of Compliance, following the procedures below, so it can be determined whether conducting an inspection of the sterilization facility is a priority.

In order to maintain consistency in our approach to non-traditional methods of sterilization, we recommend that review scientists:

1. Identify the section in the submission related to a potential non-traditional method of sterilization;
2. Refer a copy of the section to the Branch Chief, Infection Control Devices (INCB), Division of Dental, Infection Control and General Hospital Devices (DDIGD) for consideration; and

INCB will assess the above information related to the non-traditional sterilization method and provide feedback to the referring ODE division and to OC, as needed. If INCB determines that the method is actually a traditional method, rather than a non-traditional method, then INCB will advise the referring ODE division of this determination and no referral will be made to OC.

If, however, INCB determines that the sterilization method is a non-traditional method, INCB will advise the referring ODE division and direct the information to OC for appropriate action. OC will review the information provided and consult with INCB to decide if an inspection of the sterilization facility should be considered a priority in the postmarket period. For novel, non-traditional sterilization methods for which the Agency has had limited experience (i.e., those identified in Section II, B, 2 above), INCB, along with the ODE referring division director and the ODE Deputy Director for Science and Regulatory Policy, will work with OC management to decide if an inspection may be needed in the premarket period. Throughout all of the situations described above, INCB will provide technical consultation to ODE and OC on non-traditional sterilization methods, as each situation requires.

The Least Burdensome Approach

The issues identified in this guidance document represent those that we believe need to be addressed before a device can be marketed. In developing the guidance, we carefully considered the relevant statutory criteria for Agency decision-making. We also considered the burden that may be incurred by industry's attempt to comply with the guidance and address the issues we have identified. We believe that we have considered the least burdensome approach to resolving the issues presented in the guidance document. If, however, industry believes that there is a less burdensome way to address the issues, the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document should be followed. It is available on our Center web page at: http://www.fda.gov/cdrh/modact/leastburdensome.html

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

Exhibit 4

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc. a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

ARTHREX, INC.'S OBJECTIONS AND RESPONSES TO DEPUY MITEK, INC.'S FIRST SET OF REQUESTS FOR DOCUMENTS AND THINGS

Pursuant to Rule 34 of the Federal Rules of Civil Procedure and Rule 34.1 of the Local Rules of the United States District Court for the District of Massachusetts, Arthrex, Inc. ("Arthrex"), by and through its counsel, hereby responds and objects to DePuy Mitek, Inc.'s ("DePuy Mitek") First Set of Requests for Documents and Things ("the Requests") in correspondingly numbered paragraphs, first stating its general objections as follows:

GENERAL OBJECTIONS

1. Arthrex objects to the Requests to the extent they purport to impose upon Arthrex obligations exceeding those set forth in the Federal Rules of Civil Procedure, the Local Rules of the Court and applicable case law.

2. Arthrex objects to the Requests to the extent that they seek documents or information outside of Arthrex's possession, custody, or control.

3. Arthrex objects to the Requests to the extent they seek material that is not relevant to the issues in this litigation, or that is not reasonably calculated to lead to the discovery of admissible evidence.

4. Arthrex objects to the Requests to the extent they seek documents and things that, if furnished, would violate any judicial order, protective order, privacy interest, contractual obligation, non-disclosure agreement, confidentiality agreement or other confidentially obligation vis-à-vis any third party. Absent third party permission, Arthrex will not produce such documents and things unless ordered to do so by the Court.

5. Arthrex objects to the Requests to the extent they seek information that has already been (or will be) produced by or is in the possession, custody or control of a third party, as such production would impose an unnecessary and undue burden and expense on Arthrex. Moreover, Arthrex objects to the Requests to the extent they purport to require Arthrex to seek information or documents that are in the possession, custody or control of a third party, as such production would impose an unnecessary and undue burden and expense on Arthrex.

6. Arthrex objects to the Requests as being unduly burdensome to the extent they seek duplicative or cumulative information or documents.

7. Arthrex objects to the Requests to the extent they seek identifications, descriptions and/or production of "all" documents, "all" agreements, etc., as being overbroad, unduly burdensome and oppressive.

8. Arthrex objects to any requirement that it produce documents generated after the filing of this action. Such material is clearly privileged, and it is unduly burdensome to require the inclusion of such information in any privilege log.

9. Arthrex objects to the Requests to the extent they ask Arthrex to identify and disclose information from attorneys and non-testifying experts on the grounds that DePuy Mitek is not entitled to such information. Arthrex objects to the Requests to the extent that they ask Arthrex to identify and disclose information from and about experts and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court.

10. Arthrex objects to the Requests on the grounds that they are overly broad and unduly burdensome to the extent they are not limited to a specific time period.

11. Arthrex objects to the Requests to the extent they fail to describe the information requested with reasonable particularity, are indefinite as to time and scope, and/or seek information that is not relevant to the claims or defenses of the parties in this matter.

12. Arthrex objects to the Requests to the extent they seek documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Moreover, any inadvertent production of such documents will not be deemed a waiver of any privilege or immunity with respect to the information produced. Privileged documents that are otherwise responsive to any Request will be identified on a privilege log in accordance with Rule 26(b)(5) of the Federal Rules of Civil Procedure.

13. Arthrex objects to the Requests to the extent they seek trade secrets and/or confidential documents and things. Subject to the foregoing General Objections, Arthrex will produce requested documents and things to which DePuy Mitek is entitled in accordance with a protective order, when entered by the Court.

14. Arthrex objects to the Requests as unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence to the extent they seek information relating to its activities entirely outside of the United States.

15. Arthrex objects to the Requests to the extent they seek discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

16. Arthrex objects to the Requests to the extent they seek documents that no longer exist in a particular form. Where possible, subject to any applicable objection, Arthrex will produce documents as they existed as of the date requested. In those cases where this is not possible, Arthrex will produce the documents as they exist today.

17. Discovery in this matter has only recently begun. Arthrex is continuing its investigation to obtain information responsive to these document requests. Therefore, the following responses are given without prejudice to Arthrex's right to introduce documents or information discovered or deemed responsive subsequent to the date of these responses.

18. Any statements made herein regarding Arthrex's intention to provide information or documents responsive to any given document request does not necessarily indicate or imply the existence of any information or documents responsive thereto. Furthermore, any information provided or referred to herein is not deemed to be a waiver of Arthrex's objections as to the competency, relevance, privilege or admissibility as evidence in this or any subsequent proceeding or trial in this or any other action for any purpose whatsoever. In addition, Arthrex reserves the right to supplement or amend its response to the document requests based upon information, documents, and things it receives during discovery or obtains upon further investigation.

19. In gathering relevant and responsive documents, Arthrex has interpreted the Requests utilizing ordinary meanings of words and have or shall expend reasonable efforts to identify and deliver documents that appear responsive. To the extent that the Requests purport to seek documents other than as so interpreted, or requires more than

reasonable efforts to identify and deliver documents, Arthrex objects on the grounds that the Requests are vague, ambiguous and/or overbroad and unduly burdensome.

20. Arthrex objects to the Requests to the extent they seek production of documents already in DePuy Mitek's possession as a result of communications between the parties and/or document productions made by Arthrex to DePuy Mitek in connection with Arthrex, Inc. v. DePuy Mitek, Inc., Case No. 2:04-cv-328-FtM-33DNF, currently pending in the Middle District of Florida.

21. Arthrex objects to DePuy Mitek's definition of "Braided Suture Product(s)," "Arthrex Braided Suture Products," "Convoyed Braided Suture Product(s)" and "Arthrex Convoyed Braided Suture Product(s)" as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. Accordingly, to the extent DePuy Mitek's Requests for Documents and/or Things contain these defined terms, Arthrex's answers to those Requests are limited to either Arthrex's FiberWire® suture products, Arthrex products that incorporate its FiberWire® suture products, or both.

RESPONSES AND SPECIFIC OBJECTIONS

Arthrex incorporates all of the General Objections set forth above and, subject to and without waiving these Objections, further objects and responds to the numbered document requests as follows:

REQUEST NO. 1

Arthrex Organizational charts from May 24, 1994 to the present.

RESPONSE TO REQUEST NO. 1

Arthrex objects to this Request to the extent it seeks production of documents already in DePuy Mitek's possession as a result of document productions made by Arthrex to DePuy Mitek in connection with Arthrex, Inc. v. DePuy Mitek, Inc., Case No. 2:04-cv-328-FtM-33DNF, currently pending in the Middle District of Florida ("prior document productions").

Subject to and without waiving its general and specific objections, Arthrex states that it will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 2

Documents sufficient to describe each policy of Arthrex concerning document destruction or document retention from May 24, 1994 to present.

RESPONSE TO REQUEST NO. 2

Arthrex objects to this Request to the extent it seeks production of documents already in DePuy Mitek's possession as a result of document productions made by Arthrex to DePuy Mitek in connection with Arthrex, Inc. v. DePuy Mitek, Inc., Case No.

2:04-cv-328-FtM-33DNF, currently pending in the Middle District of Florida ("prior document productions").

Subject to and without waiving its general and specific objections, Arthrex states that it will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 3

All documents and things concerning the Patent-in-Suit, including, but not limited to, the files of any in-house Arthrex attorney regarding the Patent-in-Suit.

RESPONSE TO REQUEST NO. 3

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents at this time. Arthrex also objects to this Request as premature since Arthrex has not yet decided whether to rely on advice of counsel. Arthrex will supplement its Response, as necessary, in accordance with the Joint Case Management Statement and Scheduling Order entered by the Court.

Subject to and without waiving its general and specific objections, Arthrex states that it will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 4

All documents and things concerning any analysis that concerns the Patent-in-Suit, including but not limited, to analysis relating to infringement, validity, or unenforceability, willful infringement, strength, scope, clearance, or valuation of the Patent-in-Suit or any claim of the Patent-in-Suit.

RESPONSE TO REQUEST NO. 4

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents at this time. Arthrex also objects to this Request as premature since Arthrex has not yet decided whether to rely on advice of counsel. Arthrex will supplement its Response, as necessary, in accordance with the Joint Case Management Statement and Scheduling Order entered by the Court.

Subject to and without waiving its general and specific objections, Arthrex states that it will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 5

All communications between Arthrex and any person concerning the Patent-in-Suit including, but not limited to, communications with the assignee named on the cover of U.S. Patent No. 5,318,575.

RESPONSE TO REQUEST NO. 5

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 6

All opinions or communications of counsel concerning the Patent-in-Suit and all documents and things concerning such opinions or communications.

RESPONSE TO REQUEST NO. 6

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as premature since Arthrex has not yet decided whether to rely on advice of counsel. Arthrex will supplement its Response, as necessary, in accordance with the Joint Case Management Statement and Scheduling Order entered by the Court.

REQUEST NO. 7

All documents and things concerning Alastair W. Hunter, Arthur Taylor, Jr. or Mark Steckel.

RESPONSE TO REQUEST NO. 7

Arthrex objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 8

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 9 of Arthrex's Answer and Counterclaim in response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 8

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects

to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 9

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 10 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 9

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 10

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 11 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 10

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 11

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 12 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 11

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex. Arthrex

further objects to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 12

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 13 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 12

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex. Arthrex further objects to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 13

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 14 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 13

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 14

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraphs 15-17 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 14

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 15

All documents and things upon which Arthrex relies, or intends to rely, to support the Affirmative Defense in paragraph 18 of Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 15

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 16

All documents and things upon which Arthrex relies, or intends to rely, to support its Counterclaim in Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint.

RESPONSE TO REQUEST NO. 16

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 17

All documents and things upon which Arthrex relies, or intends to rely, to support its denial in Arthrex's Answer and Counterclaim in Response to DePuy Mitek's Complaint that Arthrex's infringement is willful.

RESPONSE TO REQUEST NO. 17

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request as premature since Arthrex has not yet decided whether to rely on advice of counsel. Arthrex will supplement its Response, as necessary, in accordance with the Joint Case Management Statement and Scheduling Order entered by the Court. Arthrex

further objects to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 18

All Prior Art and all documents and things concerning any Prior Art including, but not limited to, the results of any prior art searches regarding the validity or invalidity of the Patent-in-Suit.

RESPONSE TO REQUEST NO. 18

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 19

All documents and thing concerning any Arthrex foreign or United States patent or patent application that describes a braided suture.

RESPONSE TO REQUEST NO. 19

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request since the term "braided suture" is vague and indefinite. Arthrex further objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 20

All documents and things concerning the level of ordinary skill in the art of the Patent-in-Suit.

RESPONSE TO REQUEST NO. 20

Arthrex objects to this Requests to the extent that it seeks information from and about experts and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court.

REQUEST NO. 21

All documents and things that evidence or refute any secondary consideration (including, but not limited to, commercial success, long felt but unresolved need, failure of others, commercial acquiescence, and copying) that concern the nonobviousness or obviousness of the Patent-in-Suit.

RESPONSE TO REQUEST NO. 21

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 22

All documents and things that support or refute any definition, meaning, interpretation, or construction or any term, limitation, word, or element of any claim of the Patent-in-Suit espoused by either party.

RESPONSE TO REQUEST NO. 22

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex. Arthrex further objects to this Request as premature since DePuy Mitek has not yet identified

which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents, nor have the parties identified their respective claim constructions. Arthrex further objects to this Request as premature to the extent it seeks information on claim construction. Arthrex will supplement this Response at the time for claim construction set forth in the Joint Case Management Statement and Scheduling Order entered by the Court.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 23

All extrinsic evidence or material upon which Arthrex relies, or intends to rely, to support any claim construction espoused by Arthrex.

RESPONSE TO REQUEST NO. 23

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex. Arthrex further objects to this Request as premature since DePuy Mitek has not yet identified which claim(s) of the '446 patent it is asserting, the basis for its claim of infringement or whether and how there is infringement under the doctrine of equivalents. Arthrex further objects to this Request as premature to the extent it seeks information on claim construction. Arthrex will supplement this Response at the time for claim construction set forth in the Joint Case Management Statement and Scheduling Order entered by the Court.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 24

All documents and things concerning the operation, performance, material characteristics, or material properties of any Braided Suture Product or part of any Braided Suture Product.

RESPONSE TO REQUEST NO. 24

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks information already in the possession of DePuy Mitek. Arthrex further

objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 25

Documents sufficient to identify the structure and intended use of each Braided Suture Product and/or each Convoyed Braided Suture Product.

RESPONSE TO REQUEST NO. 25

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Convoyed Braided Suture Product," as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks information already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 26

All instructions for use and training materials for each Arthrex Braided Suture Product.

RESPONSE TO REQUEST NO. 26

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks information already in the possession of DePuy Mitek. Arthrex further objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 27

Documents sufficient to identify the amount of each Braided Suture Product that has been imported into the United States by or for Arthrex and when importation of each Braided Suture Product occurred.

RESPONSE TO REQUEST NO. 27

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search

REQUEST NO. 28

Each sales contract for each Braided Suture Product.

RESPONSE TO REQUEST NO. 28

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request as overly broad and unduly burdensome to the extent it seeks "each sales contract."

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 29

All documents and things concerning any acquisition or licensing by or from Arthrex of any technology concerning any Braided Suture Product.

RESPONSE TO REQUEST NO. 29

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 30

All documents and things concerning any changes or modifications to the design of any Braided Suture Product since 1998, including documents sufficient to identify the nature of such change or modification and the date such change or modification was made.

RESPONSE TO REQUEST NO. 30

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 31

All correspondence between Arthrex and the U.S. Food and Drug Administration or foreign equivalent of the U.S. Food and Drug Administration related to obtaining marketing approval for any Braided Suture Product.

RESPONSE TO REQUEST NO. 31

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the

extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex. Arthrex further objects to this Request as unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence to the extent that it seeks information relating to its activities entirely outside of the United States. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 32

All marketing materials, advertisements, press releases, news articles, and Internet web pages, concerning Arthrex's Braided Suture Product.

RESPONSE TO REQUEST NO. 32

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Arthrex's Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 33

Arthrex's financial statements, business plans, sales plans, and marketing plans concerning any Braided Suture Product.

RESPONSE TO REQUEST NO. 33

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex responds that no documents responsive to this Request exist.

REQUEST NO. 34

Periodic statements sufficient to describe Arthrex's costs for its Braided Suture Products.

RESPONSE TO REQUEST NO. 34

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 35

Documents and things sufficient to describe the market demand, including market and sales forecasts or surveys, for Braided Suture Product, including documents

concerning the actual or potential size of such market demand in dollars, units, or any other measure.

RESPONSE TO REQUEST NO. 35

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex responds that no documents responsive to this Request exist.

REQUEST NO. 36

For each fiscal quarter or other periodic summary that is less than a year, documents sufficient to identify all sales of Braided Suture Product including documents sufficient to identify the following information for each Braided Suture Product.:

a. name of the product sold;

b. product indicia used by Arthrex to identify the product;

c. number of units sold;

d. total amount of sales in dollars;

e. average per unit price in dollars; and

f. gross and net profits (or losses).

RESPONSE TO REQUEST NO. 36

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 37

Documents sufficient to identify all selling prices and pricing policies for each Braided Suture Product.

RESPONSE TO REQUEST NO. 37

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 38

For each fiscal quarter or other periodic summary that is less than a year, documents sufficient to identify all actual or proposed discounting, or policies concerning the actual or proposed discounting, of any Braided Suture Product.

RESPONSE TO REQUEST NO. 38

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 39

All documents and things that describe any technical advantages of each Braided Suture Product or reasons why customers purchase each Braided Suture Product.

RESPONSE TO REQUEST NO. 39

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 40

All documents and things that reflect Arthrex's market share for its Braided Suture Products on a monthly or quarterly basis since the introduction of Arthrex's Braided Suture Products, including any third party reports and internally created documents, and analysis of the same.

RESPONSE TO REQUEST NO. 40

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Braided Suture Product" and "Arthrex's Braided Suture Products," as defined by

DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex responds that no documents responsive to this Request exist.

REQUEST NO. 41

All documents and things concerning the date(s) on which and the circumstances under which Arthrex first became aware that DePuy Mitek claimed that any of its patents covered any Braided Suture Product.

RESPONSE TO REQUEST NO. 41

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request to the extent it seeks information already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 42

Documents sufficient to identify any person who has participated in the technical development of any Braided Suture Product (including corporate entities, business partners, engineers, designers, project managers, product managers, marketing

managers, product planners, or patent counsel, whether or not these persons are or were affiliated with Arthrex).

RESPONSE TO REQUEST NO. 42

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as being vague and ambiguous to the extent the term "participated" is undefined.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 43

Documents concerning the design and development of each Braided Suture Product including but not limited to the files and laboratory notebooks of each engineer or other person who participated in the development of each Braided Suture Product.

RESPONSE TO REQUEST NO. 43

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 44

All documents and things concerning any effort, attempt, or consideration by Arthrex or any other person to avoid infringement of the Patent-in-Suit.

RESPONSE TO REQUEST NO. 44

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 45

All documents concerning the date on which Arthrex first gained actual knowledge of the Patent-in-Suit.

RESPONSE TO REQUEST NO. 45

See Response to Request No. 41, which is incorporated herein by reference.

REQUEST NO. 46

All documents and things concerning any decision of Arthrex to select any materials for the suture used in any Braided Suture Product including but not limited to any communications with vendors that state a material preference for Arthrex's Braided Suture Product.

RESPONSE TO REQUEST NO. 46

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "Arthrex Braided Suture Product" and "Braided Suture Product," as defined by DePuy Mitek, are overly broad and include products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 47

All documents and things concerning any policy or procedure of Arthrex concerning patent infringement or non-infringement.

RESPONSE TO REQUEST NO. 47

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents.

Subject to and without waiving its general and specific objections, Arthrex responds that no documents responsive to this Request exist.

REQUEST NO. 48

All reports that were generated by, or on behalf of, any person whom Arthrex expects to call as an expert witness at any hearing or at trial.

RESPONSE TO REQUEST NO. 48

Arthrex objects to this Request to the extent that it seeks information from and about experts and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court.

REQUEST NO. 49

All documents and things relied upon or considered by any person whom Arthrex expects to call as an expert witness at any hearing or at trial.

RESPONSE TO REQUEST NO. 49

Arthrex objects to this Request to the extent that it seeks information from and about experts and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court.

REQUEST NO. 50

All documents and things considered in preparing any responses to DePuy Mitek's First Set of Interrogatories to Arthrex Inc., and all documents and things containing information responsive to any of those interrogatories.

RESPONSE TO REQUEST NO. 50

Arthrex objects to this Requests to the extent that it purports to impose upon Arthrex obligations exceeding those set forth in the Federal Rules of Civil Procedure, the Local Rules of the Court and applicable case law. Arthrex also repeats its objections stated in connection with each of DePuy Mitek's Interrogatories included in its First Set of Interrogatories, as if fully set forth herein.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 51

All customer surveys, market preference tests or surveys, or other studies concerning any Braided Suture Product.

RESPONSE TO REQUEST NO. 51

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 52

Each communication between Arthrex and any person whom Arthrex expects to call as an expert witness at any hearing or at trial.

RESPONSE TO REQUEST NO. 52

Arthrex objects to this Request to the extent that it seeks information from and about experts and any such information to which DePuy Mitek is entitled will be provided in accordance with the Federal Rules of Civil Procedure and the Joint Case Management Statement and Scheduling Order entered by the Court.

REQUEST NO. 53

Any patent infringement indemnification or patent insurance agreement that Arthrex is a party to concerning any infringement of any Braided Suture Product.

RESPONSE TO REQUEST NO. 53

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 54

Each license or agreement under which Arthrex has or is paying royalties or consideration for sutures, anchors, needles, or shoulder surgical products, instruments, or technology and royalty reports reflecting payments under any such licenses or agreements.

RESPONSE TO REQUEST NO. 54

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The terms "sutures, anchors, needles, or shoulder surgical products" are not defined, are overly

broad and oppressive and include products not relevant to the present lawsuit. Arthrex's Response to this Request is directed to Arthrex's FiberWire® suture products and Arthrex products that incorporate its FiberWire® suture products.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 55

All documents and things concerning whether the selling, licensing, providing or otherwise distributing any Braided Suture Product affects the sales of other Arthrex products and/or services.

RESPONSE TO REQUEST NO. 55

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 56

Documents sufficient to identify the structure, identity and use of any product that is sold by Arthrex as a result of or is associated with the sale of any Braided Suture Product.

RESPONSE TO REQUEST NO. 56

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term

"Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to the phrase "as a result of or is associated with" as being vague and ambiguous.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 57

For each fiscal quarter or other periodic summary that is less than a year, documents sufficient to identify all actual sales of each Convoyed Braided Suture Product including documents sufficient to identify the following information for each Convoyed Braided Suture Product:

a. name of the product sold;

b. product indicia used by Arthrex to identify the product;

c. number of units sold;

d. total amount of sales in dollars;

e. average per unit price in dollars; and

f. gross and net profits (or losses).

RESPONSE TO REQUEST NO. 57

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Convoyed Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 58

All documents that support, contradict, or otherwise relate to Arthrex's admissions, denials or other allegations set forth in paragraphs 9-18 of Arthrex's Answer and paragraph 6-8 of its counterclaim.

RESPONSE TO REQUEST NO. 58

See Responses to Request Nos. 8-16, all of which are incorporated herein by reference. In addition, subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 59

All documents concerning any comparisons between Braided Suture Product and any other product it competes with in the marketplace.

RESPONSE TO REQUEST NO. 59

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 60

All communication(s) with any non-party about this lawsuit.

RESPONSE TO REQUEST NO. 60

Arthrex objects to this Request as being overbroad, unduly burdensome and oppressive and not reasonably calculated to lead to the discovery of admissible

evidence. Arthrex further objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 61

All documents that identify Arthrex's supplier(s) of materials or components for use in each Braided Suture Product.

RESPONSE TO REQUEST NO. 61

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request to the extent it seeks documents about materials or components other than sutures.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 62

All documents that describe the tensile strength of any suture used in any Braided Suture Product with and without a coating and how the tensile strength was determined.

RESPONSE TO REQUEST NO. 62

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term

"Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 63

All documents that describe the bending strength and rigidity of any suture used in any Braided Suture Product with and without a coating and how that bending strength and rigidity was determined.

RESPONSE TO REQUEST NO. 63

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 64

All documents concerning how Arthrex defines knot slippage and knot tie down and the procedures that Arthrex's uses to determine them.

RESPONSE TO REQUEST NO. 64

Arthrex objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents. Arthrex also objects to this Request as vague and ambiguous.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 65

All documents concerning the knot slippage tests set forth in Mr. Soffen's February 20, 2004 letter to Mr. Skula, how the knot slippage was determined, why it was determined, and who decided to determine it.

RESPONSE TO REQUEST NO. 65

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent that it seeks production of "all" documents. Arthrex also objects to this Request as vague and ambiguous.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 66

All documents that identify who was involved in the tests set forth in Mr. Soffen's February 20, 2004 letter to Mr. Skula.

RESPONSE TO REQUEST NO. 66

Arthrex objects to this Request to the extent it seeks documents protected by the attorney-client privilege, the work product doctrine, or any other applicable privilege or immunity. Arthrex will not produce such protected documents. Arthrex further objects to this Request as being overbroad, unduly burdensome and oppressive to the extent

that it seeks production of "all" documents. Arthrex also objects to this Request as vague and ambiguous. Arthrex further objects to this Request to the extent it seeks information already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 67

All documents sufficient to describe the manufacturing process used to manufacture each Braided Suture Product, including but not limited to, manufacturing specifications and the manufacturing steps or processes taken to manufacture each Braided Suture Product.

RESPONSE TO REQUEST NO. 67

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex also objects to this Request to the extent that it seeks documents or information outside of Arthrex's possession, custody, or control. Arthrex further objects to this Request to the extent that it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 68

All documents concerning the nature of and the reasons for each coating used on each suture part of each Braided Suture Product.

RESPONSE TO REQUEST NO. 68

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request to the extent that it seeks discovery of information that is in the public domain and, therefore, of no greater burden for DePuy Mitek to obtain than Arthrex.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 69

All documents concerning the testing of any Braided Suture Products that have a coating, including documents concerning the suture's tensile strength, knot-slippage properties, and bending strength and rigidity.

RESPONSE TO REQUEST NO. 69

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request to the extent it seeks documents already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex will produce responsive, non-privileged documents to the extent that such documents exist and can be located with a reasonable search.

REQUEST NO. 70

All documents that support any damages claim by Arthrex including but not limited to its trial counsel's hourly rates for attorneys that worked on this litigation, bills for this lawsuit, and any agreement concerning counsel fees for defending this lawsuit.

RESPONSE TO REQUEST NO. 70

Arthrex objects to this Request as premature. Arthrex will supplement its Response to this Request, as necessary and appropriate.

THINGS TO BE PRODUCED

REQUEST NO. 1

A sample of each Braided Suture Product.

RESPONSE TO REQUEST NO. 1

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request to the extent it seeks things already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex refers DePuy Mitek to the document(s) being produced in response to Request No. 1 for a listing (by catalog number) of relevant and responsive FiberWire® suture products. Arthrex will then produce those FiberWire® suture products specifically requested by DePuy Mitek.

REQUEST NO. 2

A sample of each Convoyed Braided Suture Product.

RESPONSE TO REQUEST NO. 2

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Convoyed Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request to the extent it seeks things already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex refers DePuy Mitek to the document(s) being produced in response to Request No. 1 for a listing (by catalog number) of relevant and responsive FiberWire® suture products. Arthrex will then produce those FiberWire® suture products specifically requested by DePuy Mitek.

REQUEST NO. 3

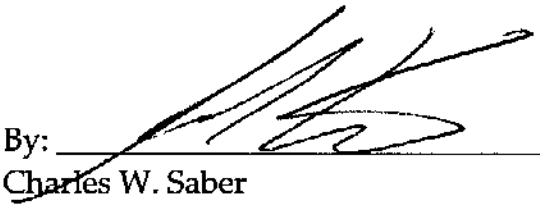
A sample of each Braided Suture Product without a coating but otherwise in its final manufacturing state (i.e., having all manufacturing process completed other and those associated with the coating).

RESPONSE TO REQUEST NO. 3

Arthrex objects to this Request as being overly broad, unduly burdensome and not reasonably calculated to lead to the discovery of admissible evidence. The term "Braided Suture Product" as defined by DePuy Mitek, is overly broad and includes products not relevant to the present lawsuit. Arthrex further objects to this Request to the extent it seeks things already in the possession of DePuy Mitek.

Subject to and without waiving its general and specific objections, Arthrex refers DePuy Mitek to the document(s) being produced in response to Request No. 1 for a listing (by catalog number) of relevant and responsive FiberWire® suture products. Arthrex will then produce those FiberWire® suture products (uncoated) specifically requested by DePuy Mitek.

Dated: February 16, 2005

By: 

Charles W. Saber
Stephen A. Soffen
Salvatore P. Tamburo
DICKSTEIN SHAPIRO MORIN
& OSHINSKY LLP
2101 L Street NW
Washington, D.C. 20037-1526
Telephone: (202) 861-9116
Facsimile: (202) 887-0689

Christopher Weld, Jr. (BBO # 522230)
Raymond P. Ausrotas (BBO # 640315)
TODD & WELD LLP
28 State Street, 31st Floor
Boston, MA 02109
Telephone: (617) 720-2626
Facsimile: (617) 227-5777

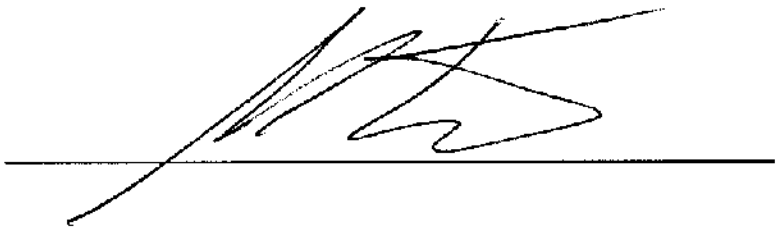
Counsel for Defendant
Arthrex, Inc.

CERTIFICATE OF SERVICE

It is hereby certified that a true and correct copy of the foregoing Arthrex, Inc.'s Objections and Responses to DePuy Mitek, Inc.'s First Set of Requests for Documents and Things has been served by Fedex overnight delivery on the following counsel for DePuy Mitek, Inc. on this 16th day of February 2005:

Lynn A. Malinoski
Woodcock Washburn, LLP
One Liberty Place, 46th Floor
Philadelphia, PA. 19103

Daniel J. Gleason
Nutter McClennan & Fish LLP
World Trade Center West
155 Seaport Boulevard
Boston, MA 02210-2604



AO 88 (11/91) Subpoena in a Civil Case

United States District Court

FOR THE DISTRICT OF LOUISIANA

Exhibit 5

DePuy Mitek, Inc.,
a Massachusetts Corporation

Plaintiff,

V.

Arthrex, Inc.,
a Delaware Corporation and

Pearsalls Ltd.,
A Private Limited Company
of the United Kingdom,

Defendants.

SUBPOENA IN A CIVIL CASE in the United States District Court for the District of Massachusetts

Case Number: 04cv12457 PBS

TO: **Debi Prasad Mukherjee**
1501 Kings Highway, P.O. Box 33932
Shreveport, Louisiana 71130

☐ YOU ARE COMMANDED to appear in the United States District Court at the place, date, and time specified below to testify in the above case.

PLACE OF TESTIMONY	COURTROOM
	DATE AND TIME

☒ YOU ARE COMMANDED to appear at the place, date, and time specified below to testify at the taking of a deposition in the above case. The deposition will be recorded by stenographic means and recorded by video and audio tape, and by instant visual display of the stenographic record.

PLACE OF DEPOSITION	DATE AND TIME
Dickstein Shapiro Morin & Oshinsky LLP 2101 L Street NW Washington, D.C. 20037-1526 USA	June 13, 2006 at 8:00 a.m.

☒ YOU ARE COMMANDED to produce and permit inspection and copying of the documents and things set forth in Schedule A attached hereto at the place, date, and time specified below:

PLACE	DATE AND TIME
Dickstein Shapiro Morin & Oshinsky LLP 2101 L Street NW Washington, D.C. 20037-1526 USA	June 13, 2006 at 8:00 a.m.

☐ YOU ARE COMMANDED to permit inspection of the following premises at the date and time specified below.

PREMISES	DATE AND TIME

Any organization not a party to this suit that is subpoenaed for the taking of a deposition shall designate one or more officers, directors, or managing agents, or other persons who consent to testify on its behalf, and may set forth, for each person designated, the matters on which the person will testify. Federal Rules of Civil Procedure, 30(b)(6).

ISSUING OFFICER SIGNATURE AND TITLE (ATTORNEY FOR PLAINTIFF)	DATE
Lynn Malinoski	6/8/06

ISSUING OFFICER'S NAME, ADDRESS AND PHONE NUMBER

Lynn Malinoski, Woodcock Washburn LLP, One Liberty Place, 46th Floor, Philadelphia, Pennsylvania 19103, 215-568-3100

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

AO 88 (11/91) Subpoena in a Civil Case

PROOF OF SERVICE

	DATE	PLACE
SERVED		
SERVED ON (PRINT NAME)		MANNER OF SERVICE
SERVED BY (PRINT NAME)		TITLE

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on _____
DATE

_____
Signature of Server

_____
Address of Server

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

© PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for depositions, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy the material or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
(I) fails to allow reasonable time for compliance;
(ii) requires a person who is not a party or an officer of a party to travel to a place

more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(b)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
(iv) subjects a person to undue burden.
(B) If a subpoena
(I) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

Schedule A

Pursuant to Rule 45 of the Federal Rules of Civil Procedure and the Local Rules of the District of Massachusetts, Plaintiff DePuy Mitek, by and through its counsel, will take the deposition upon oral examination of Debi Prasad Mukherjee beginning on June 13, 2006 at 8:00 a.m. at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street NW, Washington, D.C. 20037 USA. The deposition will be conducted before an officer authorized by law to administer oaths and will be recorded by stenographic and video means. The deposition will proceed from day to day, weekends and federal holidays excluded, until completed.

Instructions and Definitions

1. DePuy Mitek has sued Arthrex in the United States District Court for the District of Massachusetts for Arthrex's infringement of U.S. Patent No. 5,314,446. A copy of DePuy Mitek's Amended Complaint is attached as Exhibit 1.

2. "Arthrex" means Arthrex, Inc. and includes each of its predecessors, successors, subsidiaries, divisions, and departments.

3. "Concerning" means referring to, relating to, commenting upon, evidencing or embodying.

4. "Communication(s)" means any transmission of information by one or more persons or between two or more persons by any means including, but not limited to, emails, telephone conversations, letters, telegrams, teletypes, telexes, telecopies, computer linkups, written memoranda, and face-to-face conversations.

5. "You" means Debi Prasad Mukherjee.

Schedule A: Documents To Be Produced

Request No. 1

All communications between any of Arthrex, you, Dr. Gitis, Dr. Burks, and/or Dickstein, Shapiro, Morin & Oshinsky LLP concerning the lawsuit commenced by the Complaint attached as Exhibit 1.

Request No. 2

All documents and things concerning this lawsuit, including, but not limited to, documents concerning "Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446," "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-infringement of U.S. Patent No. 5,314,446 and Other Matters," and "Rebuttal Expert Report of Dr. Debi Prasad Mukherjee."

Things To Be Produced

Request No. 1

All tested and untested samples referred to in "Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446" dated March 3, 2006, and in "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-infringement of U.S. Patent No. 5,314,446 and Other Matters" dated March 24, 2006, or that Dr. Mukherjee evaluated or had in his possession, including any spools or other information concerning the samples.

Request No. 2

All tested and untested FiberWire suture samples referred to in Dr. Gitis' "Comparative Suture Testing" report dated March 23, 2006.

AFFIDAVIT

STATE OF LOUISIANA
PARISH OF CADDO

June 15, 2006

DUPUY MITEK, INC.,
a MASSACHUSETTS CORPORATION
Plaintiff(s),

-vs-

ARTHREX, INC.,
a DELAWARE CORPORATION and

PEARSALLS LTD.,
A PRIVATE LIMITED COMPANY
OF THE UNITED KINGDOM
Defendant(s).

UNITED STATES DISTRICT COURT
for the DISTRICT OF MASSACHUSETTS

Case No: 04cv12457 PBS

Regarding the service of **SUBPOENA IN A CIVIL CASE,** the *Process Server,* **WAS ABLE to effect service** of the documents provided on**: DEBI PRASAD MUKHERJEE**

Please note: The documents came in our hand on June 12, 2006 at 9:15 a.m. and **SERVICE WAS** accomplished at his place of employment [in hand] upon **DEBI PRASAD MUKHERJEE,** at 1501 Kings Hwy, Shreveport, Louisiana 71130 on June 15, 2006 at 12:10 p.m.

MS. LINDA MONTANO**,** does hereby certify that:

1. I have personal knowledge of the facts and statements contained in this affidavit and each is true and correct.
2. I am an individual not less than 18 years of age.
3. I am neither a party to, nor do I have an interest in the outcome of this case.
4. I have never been convicted of a felony or misdemeanor involving moral turpitude in any state or federal jurisdiction.

Linda Montano
Linda Montano

SUBSCRIBED AND SWORN BEFORE ME, the undersigned Notary Public on this the 15th day of June, 2006, by Linda Montano , known to me to be the person whose name is signed to this affidavit.

William Howard Malpass
Notary Public/State of Louisiana
My commission is for life
Notary #51924

(See Rule 45, Federal Rules of Civil Procedure, Parts C & D on Reverse)

AO 88 (11/91) Subpoena in a Civil Case

PROOF OF SERVICE

	DATE	PLACE
SERVED	June 15, 2006	1501 Kings Hwy.,Shreveport, La. 71130
SERVED ON (PRINT NAME)		MANNER OF SERVICE
Debi Prasad Mukherjee		person/in hand
SERVED BY (PRINT NAME)		TITLE
Linda Montano		Process Server

DECLARATION OF SERVER

I declare under penalty of perjury under the laws of the United States of America that the foregoing information contained in the Proof of Service is true and correct.

Executed on June 15, 2006
DATE

Linda T. Montano
Signature of Server

5825 Southern Ave.
Address of Server

Shreveport, La. 71106

Rule 45, Federal Rules of Civil Procedure, Parts C & D:

© PROTECTION OF PERSONS SUBJECT TO SUBPOENAS.

(1) A party or an attorney responsible for the issuance and service of a subpoena shall take reasonable steps to avoid imposing undue burden or expense on a person subject to that subpoena. The court on behalf of which the subpoena was issued shall enforce this duty and impose upon the party or attorney in breach of this duty an appropriate sanction, which may include, but is not limited to, lost earnings and a reasonable attorney's fee.

(2)(A) A person commanded to produce and permit inspection and copying of designated books, papers, documents or tangible things, or inspection of premises need not appear in person at the place of production or inspection unless commanded to appear for depositions, hearing or trial.

(B) Subject to paragraph (d)(2) of this rule, a person commanded to produce and permit inspection and copying may, within 14 days after service of the subpoena or before the time specified for compliance if such time is less than 14 days after service, serve upon the party or attorney designated in the subpoena written objection to inspection or copying of any or all of the designated materials or of the premises. If objection is made, the party serving the subpoena shall not be entitled to inspect and copy the material or inspect the premises except pursuant to an order of the court by which the subpoena was issued. If objection has been made, the party serving the subpoena may, upon notice to the person commanded to produce, move at any time for an order to compel the production. Such an order to compel production shall protect any person who is not a party or an officer of a party from significant expense resulting from the inspection and copying commanded.

(3)(A) On timely motion, the court by which a subpoena was issued shall quash or modify the subpoena if it
(I) fails to allow reasonable time for compliance;
(ii) requires a person who is not a party or an officer of a party to travel to a place

more than 100 miles from the place where that person resides, is employed or regularly transacts business in person, except that, subject to the provisions of clause (c)(3)(b)(iii) of this rule, such a person may in order to attend trial be commanded to travel from any such place within the state in which the trial is held, or
(iii) requires disclosure of privileged or other protected matter and no exception or waiver applies, or
(iv) subjects a person to undue burden.
(B) If a subpoena
(I) requires disclosure of a trade secret or other confidential research, development, or commercial information, or
(ii) requires disclosure of an unretained expert's opinion or information not describing specific events or occurrences in dispute and resulting from the expert's study made not at the request of any party, or
(iii) requires a person who is not a party or an officer of a party to incur substantial expense to travel more than 100 miles to attend trial, the court may, to protect a person subject to or affected by the subpoena, quash or modify the subpoena or, if the party in whose behalf the subpoena is issued shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship and assures that the person to whom the subpoena is addressed will be reasonably compensated, the court may order appearance or production only upon specified conditions.

(d) DUTIES IN RESPONDING TO SUBPOENA

(1) A person responding to a subpoena to produce documents shall produce them as they are kept in the usual course of business or shall organize and label them to correspond with the categories in the demand.

(2) When information subject to a subpoena is withheld on a claim that it is privileged or subject to protection as trial preparation materials, the claim shall be made expressly and shall be supported by a description of the nature of the documents, communications, or things not produced that is sufficient to enable the demanding party to contest the claim.

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

DePuy Mitek, Inc. a Massachusetts Corporation Plaintiff, v. Arthrex, Inc., *et al.* a Delaware Corporation Defendant.	)	Civil Action No. 04-12457 PBS

DECLARATION OF DR. DEBI PRASAD MUKHERJEE IN SUPPORT OF DEFENDANTS' OPPOSITION TO PLAINTIFF DEPUY MITEK'S MOTION TO STRIKE HEARSAY EXHIBIT AND ALL CITATION AND COMMENTARY THERETO

1. My name is Dr. Debi Prasad Mukherjee. I am an Associate Professor and the Coordinator of Bioengineering in the Department of Orthopaedic Surgery at the Louisiana State University Health Sciences Center, in Shreveport, Louisiana. My CV is attached as Ex. A.

2. I am the same Dr. Debi Prasad Mukherjee who prepared the "Expert Report of Dr. Debi Prasad Mukherjee Concerning Invalidity of U.S. Patent No. 5,314,446" dated March 3, 2006, the "Responsive Expert Report of Dr. Debi Prasad Mukherjee Concerning Non-Infringement of U.S. Patent No. 5,314,446 and Other Matters" dated March 24, 2006, and the "Rebuttal Expert Report of Dr. Debi Prasad Mukherjee" dated April 13, 2006.

3. I understand that Spectra is a known trade name for UHMWPE and that manufacturers' brochures such as the brochure published by Allied Fibers Technical Center entitled "SPECTRA EXTENDED CHAIN POLYETHYLENE FIBERS" (Ex. B) ("the SPECTRA brochure") are the best sources of information since the manufacturers of these types of products are in the best

position to provide accurate descriptions of their product, the history of their product development and a comparison to related products.

4. The Spectra brochure supports the opinions I provided in this case regarding the differences between general purpose PE and UHMWPE, including my opinion that in 1992, UHMWPE was a well-known, highly specialized fiber material with strength properties that are far superior to that of general purpose PE.

5. I have reviewed sections 1 & 2 of the Spectra brochure and, as described below, it is my opinion that the subject matter included in those sections is reliable and accurate.

6. Specifically, it is my opinion that the SPECTRA brochure is reliable and accurate in stating that UHMWPE is one of the strongest synthetic fibers ever created. Ex. B at § 1. *See, e.g.*, Ex. C at 5-26.

7. It is also my opinion that the SPECTRA brochure is reliable and accurate in stating that general purpose polyethylene has been used in industry for decades and has established itself as a general purpose commodity polymer. Ex. B at § 1.

8. It is further my opinion that the SPECTRA brochure is reliable and accurate in stating that since its introduction in fiber form in the 1980s, UHMWPE, has been considered a specialized high performance product. Ex. B at § 1. *See, e.g.*, Ex. D at 4.

9. It is my opinion that the SPECTRA brochure is reliable and accurate in stating that the key structural characteristics – molecular weight and molecular structure – of UHMWPE are very different than that of general purpose PE. Ex. B at § 2. *See, e.g.*, Ex. D at 4.

10. It is further my opinion that the SPECTRA brochure is reliable and accurate in stating that UHMWPE has a molecular weight in the range of approximately 1 to 5 million, whereas general purpose PE has a molecular weight of typically 50,000 up to several hundred thousand. Ex. B at § 2. See, e.g., Ex. D at 4.

11. It is also my opinion that the SPECTRA brochure is reliable and accurate in stating that UHMWPE exhibits a much higher degree of crystalline orientation as compared with general purpose PE and that those differences in molecular structure are the basis for UHMWPE's superior strength characteristics. Ex. B at § 2. Ex. D at 4, 6.

I hereby declare under penalty of perjury that the foregoing is true and correct.

Executed on: Sept 15, 2006

Debi Prasad Mukherjee

Dr. Debi Prasad Mukherjee

EXHIBIT A

CURRICULUM VITAE

Name

Debi Prasad Mukherjee, Sc.D.

Title

Associate Professor and Coordinator of Bioengineering
Department of Orthopaedic Surgery
Louisiana State University Health Sciences Center

Address

1501 Kings Highway, P.O. Box 33932
Shreveport, Louisiana 71130

Telephone: (318) 675-6187
Fax: (318) 675-6186

Date of Birth

October 26, 1939

Family

Wife: Bandana
Sons: Avik
Shomik

Education

1961 B.Ch.E. (Hons), Chemical Engineering, Jadavpur University
1965 S.M., Biochemical Engineering, M.I.T.
1965 S.M., Chemical Engineering, M.I.T.
1967 Ch.E., Chemical Engineering, M.I.T.
1969 Sc.D., Chemical Engineering, M.I.T.
1980 M.B.A., Business Administration, University of Connecticut

Employment History

1992-Present Associate Professor and Coordinator of Bioengineering
Louisiana State University Health Sciences Center, Shreveport, Louisiana

1991-1992 Development Scientist
Union Carbide, Bound Brook, New Jersey

1987 - 1990 Research Program Manager
Dow Corning Wright, Arlington, Tennessee

1974 - 1987 Technical Specialist, Biomaterials
Group Leader, Extrusion & Materials Development
Senior Research Engineer

Davis & Geck, American Cyanamid Company, Danbury, Connecticut

1969 - 1974 Senior Research Engineer
The Goodyear Tire & Rubber Company, Akron, Ohio

Academic Appointment

1989 - 1993 Adjunct Associate Professor, Biomedical Engineering
Memphis State University, Memphis, Tennessee

1992 - Present Adjunct Associate Professor, Biomedical Engineering
Louisiana Tech, Ruston, LA.

Thesis Supervised

1. M.S. Thesis (1992) by J. D. Ray Jr. "A Comparison of Fatigue Behavior for APC-2/AS4 and Commingled PEEK/AS-4 Composite", Dept. of Biomedical Engineering, Memphis State University, Memphis, TN.

2. M.S. Thesis (1992) by R. R. Shults, "A Characterization Study of Hydroxylapatite Coatings on Titanium Alloy Implant Material Before and After Fatigue", Dept. of Biomedical Engineering, Memphis State University, Memphis, TN.

3. M.S. Thesis (1993) by H. A. Mansour, "Bone/Prosthesis Relative Rigidity as an Important Parameter in the Isoelasticity of Total Hip Arthroplasty of the Human Proximal Femur", Department of Biomedical Engineering, Memphis State University, Memphis, TN.

4. M.S. Thesis (1994) by P. R. Menon, "Composites of Hydroxylapatite with Water Soluble or Biodegradable Polymers as a Synthetic Bone Graft Material", Louisiana Tech University, Ruston, LA.

5. M.S. Thesis (1996), by S. Ashroff, "Effect of Crystallinity of Hydroxyapatite Coating on Titanium Implants After Cyclic Fatigue Loading", Louisiana Tech University, Ruston, LA.

6. M.S. Thesis (1996), by N.R. Dorairaj, "Effects of Cyclic Fatigue Loading on the Stability of Hydroxyapatite Coated Titanium Dental Implants in the Presence of the Periodontal Pathogens", Louisiana Tech University, Ruston, LA.

7. M.S. Thesis (1999) by J.R.Hunter, "The measurement of Stress shielding and Relative Rigidity Mismatch within the femur prosthesis union of Total Hip Replacement" Louisiana Tech University, Ruston, LA.

8. Ph.D. Thesis (2001) by Kelly Crittenden, "Evaluation of 135- and 150-degree

Sliding hip screws". Louisiana Tech University, Ruston, LA.

Honors and Awards

1. MNC Memorial Medal for securing the highest grade in the Sophomore Class of the Chemical Engineering Department, 1958.

2. E.F Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A study of burst fracture in a canine model, Louisiana Orthopaedic Association, Harry Morris Award, 1993.

3. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: "Comparison of Fixation of Locking Head and Conventional Screws in Fracture and Reconstruction Models." Winner of American College of Oral and Maxillofacial Surgeons Resident Research Award 18th Annual Meeting, San Diego, CA.,1997.

4. JW Sikes, BR Smith, and DP Mukherjee: "Effect of Bony Buttressing in the Atrophic Edentulous Mandible: An In Vitro Study." Winner of ITI Straumann Research Award, AAOMS 80th Annual Meeting, September 1998.

5. R Bhati, DP Mukherjee, KJ McCarthy, S Rogers, and DF Smith: "The Effect of Fibronectin Coating on the growth of Chondrocytes into a Biodegradable Scaffold." National Student Research Forum- The University of Texas Medical Branch of Galveston Texas, Department of Orthopaedic and Rehabilitation Award, 2000.

Editorial Board

Journal of Long Term Effect of Medical Implants
(Member of Editorial Advisory Board) 1998- Present

Journal of Biomedical Materials Research (Applied Biomaterials)
(Member of Editorial Board) 1998-2002.

Conferences Organized

Akron Polymer Lecture Group

Secretary, 1972
Program Chairman, 1973

14th Southern Biomedical Engineering Conference

Chairman
April 7-9, 1995, Shreveport, LA

Technical Sessions Chaired

Biomaterials:

11th Southern Biomedical Engineering, Memphis, TN (1992), Session Chairman

Determination of Bone Properties:

12th Southern Biomedical Engineering, New Orleans, LA (1993), Session Chairman

Biomechanics and Biomedical Engineering Symposium

Orthopaedics Biomechanics I: 31st Annual Technical Meeting of the Society of Engineering Science, Texas A&M (1994) Session Co-Chairman

Orthopaedic Biomechanics

13th Southern Biomedical Engineering, Washington, D.C. (1994)- Session Chairman

Dental Materials: natural dentition polymers and composites

Sixth World Biomaterials Congress, Hawaii (2000) Session Co-moderator

Polymers in Orthopaedics Symposium (American Chemical Society) August 2002

Chaired the session

Public/Community Service Activities

NIH Proposal Evaluations and Site Visits:

1. Reviewed the contracts on the bioerodible drug-delivery systems and was invited to a site visit to SRI on May 5-7, 1987, by the Contraceptive Development Branch, Center for Population Research, National Institutes of Health and Human Development - NIH contract, Dr. Dinesh Sharma.
2. Reviewed a number of proposal on drug-delivery systems and was invited for a working group in Bethesda, Maryland, on April 27, 1990, NIH contacts, Dr. H. Khan and Dr. D. Sharma.

3. Reviewed proposals on "Development and Testing of New Spermicides for National Institute of Child Health and Development", Bethesda, MD. June 16-17, 1992, NIH contact, Dr. S. Strenfert.
4. Special Study Section - Small Business Innovation Research (SBIR) Program, Rockville, MD, July 6-8, 1994, NIH contact, Dr. N. Vydelingum.
5. Task Group Chair, Scaffold Biomaterials Section, American Society of Testing and Materials (ASTM) 1998- 2001

Institute Activities

1992 - Present	Mentor ;Minority High School Student Research Apprentice Program
1992 - Present	Mentor: Summer Medical Student Research Program
1994 - 1995	Member of the Medical Communication Committee
1998-at present	Mentor: Science Medicine Academic Research Training Program
2001- Present	Flag Group Leader: Module III-New curriculum of instructions to Freshman/Sophomore Medical Students
2003-Present	Member of Institutional Review Board

Invited Lecturer:

Baylor College of Medicine, Department of Orthopaedic Surgery, -Grand Round – Plaster of Paris as a vehicle for delivery of tobramycin to treat Osteomyelitis, March, 13, 1994

Biomaterials Seminar in Atlanta: Technomic Publishing Co. Inc.
Tissue Engineering Applications of Bioabsorbable Polymers, November 16, 1999

Baylor College of Medicine, Department of Orthopaedic Surgery, - Grand Round Baylor University Medical center, Houston, TX, Meniscal Repair, May 7, 2003

Society Membership

Orthopaedic Research Society
Society for Biomaterials
American Association of Advancement of Science

Research Support and Meeting Grants

1. American Heart Association, Akron Chapter, December 10, 1973, for the project, The Relationship of Dynamic Mechanical Properties of Arteriosclerotic Tissue to the Deposit of Cholesterol and Its Ester, jointly with Dr. Thomas Pynadath of Kent State University, Kent, Ohio 44242, $8030.00

2. School of Dentistry, LSU Medical Center, and New Orleans. "Biomechanical In Vitro testing of the stability of HA coating etc.", jointly with Dr. J. Wittenberg, Department of Surgery, Division of Oral and Maxillofacial Surgery LSUMC-S, 1993, $7500.00.

3. ExacTech Inc., Gainesville, FL. "Experimental testing of components comprising the ExacTech 913 Knee System." 1993, $150.00

4. Whitaker Foundation: Fourteenth Southern Biomedical Engineering Conference, 1994, $6,000.00.

5. Smith & Nephew Richards: Fourteenth Southern Biomedical Engineering Conference, 1994, $1,000.00.

6. Sofamor Danek Medical: Fourteenth Southern Biomedical Engineering Conference, 1994, $300.00.

7. Dean - LSU School of Medicine-Shreveport: Fourteenth Southern Biomedical Engineering Conference, 1994, $4,500.00.

8. Center of Excellence for Arthritis & Rheumatology: 1992-1994, $37,070.00

9. Ortho-Care, Inc: 1994, $550.00.

10. Chitogenics, Inc.: Nov. 1995-May 1996, Evaluation of the carboxymethyl chitosan (NOCC) and hydroxyapatite composite paste for repairing bone defects in a rat model. Feasibility of using NOCC to complex with the hyaluronic acid to reduce the drop of viscosity of synovial fluids of the rheumatoid patients. $10,000.00.

11. Intramural Grant: January 1, 1997 - December 31, 1997. Tissue Engineering - Development of Scaffolds seeded with Different Cell types on a biodegradable matrix. $5,000.00.

12. Wright Medical Technology: June 15, 1997 - Feb. 1999. Measurement of Creep Properties of Bone Cement. $15,000.00

13. Louisiana Board of Regents: Travel Grant for Emerging Faculty. $500.00.

14. Celanese Acetate: November, 15, 1998- November 15, 1999. Feasibility study of modification of cellulose acetate filters (CAF) by gamma and electron beam radiations. $7,060.00.

15. Board of Regents Support fund, June 2000-June 2001 with matching grant from LSUHSC: Replacement of Biaxial Testing machine (Instron Model 1321) by a new digital biaxial machine (Model 8874): **$117,732.**

16. Clinical and Industrial technology Company, July 2000- July 2001: A New Vibration Mixer for Bone Cement: **$14,000**.

17. Department of Obstetrics & Gynecology , 2002-2003: "Biomechanical Studies on several Sutures". **$3420.**

18. W.L.Gore and Associates, Biodegradable Scaffold for Tissue Engineering , Jan -May 2004, **$5000.**

PUBLICATIONS

Research Thesis

D. P. Mukherjee, The Viscoelastic Properties of Elastin, Sc.D. Thesis in the Department of Chemical Engineering, M.I.T., January 13 (1969).

Papers and Abstracts of Presentations

1. DP Mukherjee and A.S. Hoffman: The Viscoelastic Properties of Elastin. Presented at the Third Biophysics Congress, August (1969).

2. A.S. Hoffman and DP Mukherjee: long-range Interactions of Cationic Sites in Elastin. Presented at the Conference on Engineering in Medicine and Biology, October 31(1971).

3. DP Mukherjee and C. Goldstein: The Mechanical and Optical Properties of Alternating and Random Copolymers of Acrylonitrile and Butadiene at the Same Acrylonitrile Content. Polymer Preprints, Vol. 14, No. 1, 36-39, (1973).

4. DP Mukherjee and C Goldstein: The Mechanical and Optical Properties of an Alternating and Emulsion NBR. Rubber Chemistry and Technology, 46, 1264-1273, (1973).

5. DP Mukherjee, AS Hoffman, and C Franzblau: The Physical Properties and Molecular Structure of Ligamentum Nuchae Elastin. Biopolymer, Vol. 13, 2447-2459, (1974).

6. DP Mukherjee and MC Morris: Rheological Properties of Synthetic Poly (isoprene) and Natural Rubber. Presented at the Annual Meeting of the Society of Rheology, Amherst, Massachusetts, October, (1974).

7. DP Mukherjee: Simultaneous Stress-Strain and Stress-Birefringence Studies on Natural Rubber, Isomerized Natural Rubber and Synthetic Poly (isoprene). Rubber Chemistry and Technology, Vol. 47, No. 5,1234-1240, (1974).

8. DP Mukherjee, H.M. Kagan, R.E. Jordan, and C. Franzblau: Effect of Hydrophobic Elastin Ligands on the Stress-Strain Properties of Elastin Fibers. Connective Tissue Research, 4, No. 3, 177-179, (1976).

9. DP Mukherjee and TI Pynadath: The Relationship of Dynamic Mechanical Properties of Arteriosclerotic Tissue of Cholesterol and Cholesterol Ester Levels of Serum and Aortic Tissues During Early Stages of Development of Atherosclerosis. Atherosclerosis, 26, 311-318, (1977).

10. DP Mukherjee: A Study of Flow Properties of Rubbers Using Rheometrics Mechanical Spectrometer. Polymer Engineering and Science, November 17, No. 1, 788-792, (1977).

11. AR Katz, D.P. Mukherjee, AL Kaganov, and S Gordon: A New Synthetic Monofilament Absorbable Suture Made from Polytrimethylene Carbonate. Surgery. Gynecology and Obstetrics, September, Vol. 161, 213-222, (1985).

12. DP Mukherjee and C Sandock: Effect of Gamma Irradiation on the Properties of the Glycolide/Trimethylene Carbonate Copolymer Maxon® Suture. The Third World Biomaterials Congress, April 21-25, 1988, Kyoto, Japan.

13. DP Mukherjee and JG Brooks, Jr.: Mechanical and Non-Destructive Evaluations of a Carbon/Carbon Composite Material. 37th Annual Meeting, Orthopedic Research Society, March 4-7,1991, Anaheim, California, 498.

14. DP Mukherjee and S Saha: Isoelasticity: A Design Consideration of Total Hip Replacement. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 25-27.

15. S Saha and DP Mukherjee: Use of Composite Materials for Total Hip Arthroplasty. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 93-96.

16. JD Ray and DP Mukherjee: A Comparison of Fatigue Properties of Carbon Fiber/PEEK Composites. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 142-144.

17. RR Shults, DP Mukherjee, and JD Ray: A Study of Hydroxylapatite Coated Titanium Alloy Material After Fatigue. Digest of Papers 11th Southern Biomedical Engineering, October 2-4, 1992, Memphis, TN, pp 159-161.

18. JJ Lorio, RN Kruse, DP Mukherjee, and JA Albright: Compressive Strength and Quantitative CT Measurements of Cancellous Bone Sample. 34th National Student Research Forum. The University of Texas Medical Branch, Galveston, Texas, April 15-17, 1993.

19. JJ Lorio, RN Kruse, DP Mukherjee, and JA Albright: Quantitative Computer Tomography (QCT) and Mechanical Properties of Cancellous Bone. Proceedings of the Twelfth Southern Biomedical Engineering Conference, New Orleans, LA, April 2-4, 1993, pp 242-244.

20. RN Kruse, DP Mukherjee, and JA Albright: A Method of Quantitative Analysis of Computed Tomography (QCT) Scan of Bone Samples Using a Sun Workstation. Proceedings of the Twelfth Southern Biomedical Engineering Conference, New Orleans, LA, April 2-4, 1993, pp 37-39.

21. DP Mukherjee, T Sweo, and JA Albright: A Comparative Study of Femoral Neck Fracture Fixation by a Compression Screw or Knowles Pins. First Joint ASCE/ASME

Summer Meeting and SES 30th Annual Meeting: Biomaterials and Biomechanics Symposium, Charlottesville, VA, June 6-9, 1993, pp 61.

22. DP Mukherjee and S. Saha: The Application of New Composite Materials for Total Joint Arthroplasty. Journal of Long Term Effects of Medical Implants, 3 (2): 131-141 (1993).

23. AD McBride, DP Mukherjee, RN Kruse, and JA Albright: Anterior Screw Fixation of Type II Odontoid Fractures: A Biomechanical Study. Poster presentation 21st Cervical Spine Research Society Meeting, New York, December 1-4, 1993.

24. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: Relationship Between Bone Mineral Density and Burst Fracture Load: A Biomechanical Study. Transactions of Orthopaedic Research Society, 19(2): 530, 1994.

25. DP Mukherjee, JM Wittenberg, SH Rogers, RN Kruse, and JA Albright: Surface Changes of Hydroxyapatite Coated Dental Implants After Cyclic Loading. Transactions 20th Annual Meeting of the Society for Biomaterials, 17:7, 1994.

26. JD Ray Jr., DP Mukherjee, and JD Ray: The Fatigue Properties of Carbon Fiber/PEEK Composites: Transactions 20th Annual Meeting of the Society for Biomaterial, 17:161, 1994.

27. RR Shults, DP Mukherjee, and JD Ray: A Study of Fatigue Properties of Hydroxyapatite Coated Titanium Alloy Implant Materials. Transactions 20th Annual Meeting for the Society for Biomaterials, 17:333, 1994.

28. DP Mukherjee, S Rogers, S Foster, KK Sadasivan, and JA Albright: A Histological Study of Polyethylene Particles in a Rabbit Model. Transactions of the 20th Annual Meeting of the Society for Biomaterials, 17:392, 1994.

29. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Comparative Biomechanical Evaluation of the Thoracolumbar Burst Fracture in Human and Canine Specimens. Orthopaedic Transactions, J Bone Joint Surg., 18(2): 517, 1994.

30. AD McBride, DP Mukherjee, RN Kruse, and JA Albright: A Biomechanical Study of Anterior Screw Fixation of Type II Odontoid Fractures. Poster Presentation, North American Spine Society and Japanese Spine Research Society, Spine Across the Sea, Maui, Hawaii, April 18-21, 1994.

31. J.E. Broyles, DP Mukherjee, and JA Albright: Application of the Photoelastic Coating Technique to Measure Strain in the Talar Neck. 35th Annual National Student Research Forum, University of Texas Medical Branch at Galveston, TX, 79, April 28-30, 1994.

32. RF Favret, DP Mukherjee, RN Kruse, and JA Albright: Analysis of Compressive Strength and Dual X-ray Absorptiometry Evaluation of Cancellous Bone Grafts. Biomedical

Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 158-161.

33. W Johnson, C.M Hymel, DP Mukherjee, and JA Albright: Crosslink Density and Water Content in Intervertebral Discs. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 689-692.

34. D York, DP Mukherjee, SH Rogers, AW Pearsall, KK Sadasivan, and JA Albright: An Evaluation of Implants and Tissues Retrieved After Orthopaedic Surgery. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 736-738.

35. PR Menon, RL Seaman, and DP Mukherjee: Development of a Composite of Polyethylene Oxide and Hydroxyapatite as a Bone Graft Substitute. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 772-774.

36. JE Broyles, RN Kruse, DP Mukherjee and JA Albright: Application of the Photoelastic Coating Technique to Measure Strain in the Talar Neck. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 856-859.

37. DP Mukherjee, SQ Hayat, C Mocek, S Foster, V Hall, and RE Wolf: Shear Viscosity and Cytokines in Rheumatoid Synovial Fluids. Biomedical Engineering Recent Developments, ed. J. Vossoughi, Proceedings of the 13th Southern Biomedical Engineering Conference, April 16-17, 1994, pp 1081-1084.

38. SQ Hayat, V Hall, DP Mukherjee, and RE Wolf: Cytokines in rheumatoid Arthritis: Synovial Fluid and Serum Levels. Presented at the American College of Rheumatology Regional Meeting, May 13-15, 1994.

39. S Saha and DP Mukherjee: Use of Composite Materials for Total Joint Replacement. Proceedings of the 31st Annual Technical Meeting of the Society of Engineering Science, Biomechanics and Biomedical Engineering Symposium, Texas A&M University, October 10-12, 1994, pp 125.

40. H Mansour, JD Ray, M Yen, and DP Mukherjee: A biomechanical Study of Stress Shielding of the Femoral Component of Orthopaedic Hip Implants. Proceedings of the 31st Annual Technical Meeting of the Society of Engineering Science, Biomechanics and Biomedical Engineering Symposium, Texas A&M University, October 10-12, 1994, pp 171.

41. JM Wittenberg, DP Mukherjee, and BR Smith: Biomechanical Evaluation of a New Fixation Device for Mandibular Angle Fractures. Supplement to Journal of Oral and Maxillofacial Surgery, 52(B), Suppl. 2, Aug. 1994, pp 107.

42. W Johnson, C.M Hymel, DP Mukherjee, and JA Albright: Crosslink Density and Water Content in Intervertebral Discs. Journal of Long-Term Effects of Medical Implants, 4(1): 20, 1994

43. J.E. Broyles, RN Kruse, DP Mukherjee, and JA Albright: Application of the Photoelastic Coating Technique to Measure Strain in the Talar Neck. Journal of Long-Term Effects of Medical Implants, 4(1): 21-22, 1994.

44. DP Mukherjee, SQ Hayat, C Mocek, S Foster, V Hall, and RE Wolf: Shear Viscosity and Cytokines in Rheumatoid Synovial Fluid. Journal of Long-Term Effects of Medical Implants, 4(1): 23, 1994.

45. PR Menon, RL Seaman, and DP Mukherjee: Development of a Composite of Polyethylene Oxide and Hydroxylapatite as a Bone Graft Substitute. Journal of Long-Term Effects of Medical Implants, 4(1): 40, 1994.

46. AD McBride, DP Mukherjee, RN Kruse, and JA Albright: Anterior Screw Fixation of Type II Odontoid Fractures: A Biomechanical Study. Spine, 20(17) No1: 1855-1859, 1995.

47. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Thoracolumbar Pedicle Screw Fixation with Zero, 1 or 2 Crosslinks. AOA Resident Conference in Pittsburgh, Mar. 1995.

48. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Method to Characterize Burst Fractures. AOA Resident Conference in Pittsburgh, Mar. 1995.

49. DP Mukherjee, J.M. Wittenberg, SH Rogers, RN Kruse, and JA Albright: A Fatigue Study of Hydroxyapatite Coated Dental Implants. Transactions of the 21st Annual Meeting of Society for Biomaterials, 18, 283, 1995.

50. MP Langford, JA Schulman, DP Mukherjee, and JP Ganley: Effects of Vitreal Substitutes (Healon, Chitosan and Vitreon) on Epithelial Cells and Human Peripheral Blood Lymphocytes. Proceedings of the 14th Southern Biomedical Engineering, 286-288, 1995.

51. K Coward, B Smith, RN Kruse, and DP Mukherjee: A Biomechanical Study of Mandibular Fracture Fixation Plates in a Bovine Rib Model. Proceedings of the 14th Southern Biomedical Engineering Meeting, 87-89, 1995.

52. JM Wittenberg, BR Smith, RN Kruse, and DP Mukherjee: A Study of Mandibular Fracture Fixation by Different Plate Designs. Proceedings of the 14th Southern Biomedical Engineering Meeting, 46-48, 1995.

53. G. Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: A Biomechanical Study of 150 vs 135-Degree Hip Screws in Femoral Neck Fractures. Proceedings of the 14th Southern Biomedical Engineering Meeting, 49-50, 1995.

54. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Method to Characterize Burst Fractures. Proceedings of the 14th Southern Biomedical Engineering Meeting, 51-52, 1995.

55. HA Mansour, JD Ray, and DP Mukherjee: Stress Shielding of Femoral Hip Components With and Without Collar. Proceedings of the 14th Southern Biomedical Engineering Meeting, 53-54, 1995.

56. SM Atchison, DP Mukherjee, RN Kruse, R Mayeux, and JA Albright: Internal Fixation of Transverse Acetabular Fractures. Proceedings of the 14th Southern Biomedical Engineering Meeting, 55-56, 1995.

57. RB Lurate, DP Mukherjee, RN Kruse, and JA Albright: Fixation of Osteochondral Fractures with Absorbable Pins. Proceedings of the 14th Southern Biomedical Engineering Meeting, 57-58, 1995.

58. PR Menon, SA Napper, and DP Mukherjee: Development of a Composite Hydroxylapatite and Chitosan as a Bone Graft Substitute. Proceedings of the 14th Southern Biomedical Engineering Meeting, 95-97, 1995.

59. DP Mukherjee, D Smith, V Hall, and RE Wolf: Relationship of Viscosity and Hyaluronic Acid Content and Molecular Weight in Synovial Fluids of Rheumatoid Arthritis Patients. American College of Rheumatology, 38, No. 6 (Supplement), R23, June 1995.

60. Eric F Berkman, Debi P Mukherjee, and James A Albright: Plaster of Paris as a Vehicle for Tobramycin. Musculoskeletal Infection Society Annual Meeting, Snow Mass, Colorado, August 10-12, 1995.

61. DP. Mukherjee, RF Favret, RN Kruse, JA. Albright, and AB Chausmer: Compressive Strength and Bone Mineral Density (DEXA) of Trabecular Bone From Vertebral Bodies. American Society for Bone and Mineral Research, 17th Annual Meeting, Baltimore, Maryland, September 10, 1995.

62. MP Langford, Joel A Schulman, Debi P Mukherjee, and James P Ganley: Effects of Healon ®, N1O Carboxyl Methyl Chitosan and Vitreon on Conjunctival Cells and Human Peripheral Blood Lymphocytes. Journal of Long Term Implants, Vol 5 (1), 1995.

63. PR Menon, SA Napper, and DP Mukherjee: Development of a Composite of Hydroxylapatite and Chitosan as a Bone Graft Substitute. Journal of Long Term Implants, Vol 5 (1), 1995.

64. JA Albright, E.F Berkman, and DP Mukherjee: Plaster of Paris as a Vehicle for Tobramycin. Biomedical Engineering Society, Annual Fall Meeting, Boston, Oct. 6-8, 1995.

65. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Mechanical Stability of Thoracolumbar Pedicle Screw Fixation with Two, And Zero Crosslinks. Biomedical Engineering Society, Annual Fall Meeting, Boston, Oct. 6-8, 1995.

66. D Mukherjee, R Favret, R Kruse, JA Albright, and AB Chausmer: Correlation of Compressive Strength of Trabecular Bone of Vertebral bodies to Bone Mineral Density by Dual Energy X-ray Absorptiometry (DEXA). Transactions of the 2nd Combined Meeting of the Orthopaedic Research Societies of U.S.A., Japan, Canada and Europe, Nov. 5-8, 244, 1995.

67. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Thoracolumbar Pedicle Screw Fixation with Zero, 1 or 2 Crosslinks. Orthopaedic Transactions (The Journal of Bone and Joint Surgery) 19(3), 727, 1995-96.

68. EF Berkman, RN Kruse, DP Mukherjee, KK Sadasivan, and JA Albright: A Method to Characterize Burst Fractures. Orthopaedic Transactions (Journal of Bone and Joint Surgery), 19(3), 731, 1995-96.

69. S Ashroff, SA Napper, PN Hale Jr., U Siriwardane, and DP Mukherjee: Stability of Hydroxyapatite Coating of Different Crystallinities on a Titanium Alloy Implant Material After Cyclic Fatigue. Proceedings of the Fifteenth Southern Biomedical Engineering Conference, 14-17, 1996

70. G Germany, S Rogers, and DP Mukherjee: A Histological Study of Polyethylene Wear Particles in a Rabbit Model. Proceedings of the Fifteenth Southern Biomedical Engineering Conference, 178-199, 1996.

71. S Mukherjee, SH Rogers, RH Mayeux, and DP Mukherjee: A Study of Achilles Tendon Rupture. Proceedings of the Fifteenth Southern Biomedical Engineering Conference, 381-383, 1996.

72. DP Mukherjee, SH Rogers, KK Sadasivan, D.G. Schmidt, MA Meyer, and JA Albright: Effects of Polyethylene Particles on Rabbit Knee Joints. Transactions of the Fifth World Biomaterials Congress, May 29-June 2, 902, 1996.

73. TC Mitchell, DP Mukherjee, and JA Albright: Plaster of Paris as a Vehicle for Vancomycin. Musculoskeletal Infection Society, August 1-3, 1996.

74. DP Mukherjee, E.F Berkman, TC Mitchell, and JA Albright: Treatment of Osteomyelitis by Tobramycin Impregnated Plaster of Paris, Musculoskeletal Infection Society, August 1-3, 1996.

75. S Ashroff, SA Napper, PN Hale Jr., U Siriwardane, and DP Mukherjee: Cyclic Fatigue of Hydroxyapatite Coated Titanium Alloy Implant Material - Effect of Crystallinity. J of Long-Term Effects of Medical Implants, 6(3&4):143-155, 1996.

76. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: Comparison of Fixation Strength between Reconstruction Plates with Locking-Head and Conventional Screws. J. Oral Maxillofacial Surg. 54(Suppl. 3); 39-40, 1996.

77. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: Comparison of the Fixation Strength between Reconstruction Plates with Conventional and Locking-Head Screws. Oral Abstract, American Association of Oral and Maxillofacial Surgeons National Meeting, Miami, FL., Sept. 18, 1996.

78. M Pearson, DP Mukherjee, F Mire, and AB Chausmer: A Method To Evaluate a Synthetic Bone Growth Material in A Rat Model Using Dual Energy X-ray Absorptiometry (DEXA). Poster presentation Intramural Society for Clinical Densitometry. January 16-19, 1997.

79. CD Clark, RH Mayeux, M Palmer, DP Mukherjee, KK Sadasivan, and JA Albright: A Biomechanical Evaluation of a Posterior Glenohumeral Lesion. Orthopaedic Transactions (ORS), J Bone Joint Surg, 20(3): 800, 1996-1997.

80. DP Mukherjee, JA Albright, AW Pearsall, RH Mayeux, and WM Palmer: A Biomechanical Study of Posterior Cruciate Ligament Fixation. Scientific Exhibit American Academy of Orthopaedic Surgeons, 64th Annual meeting, February 13-17, 1997.

81. NR Dorairaj, D.Mills, RD Berg, DP Mukherjee, and JA Albright: Cyclic Fatigue of Hydroxyapatite Coated Titanium Alloy Dental Implants after Exposure to a Periodontal Pathogen. Transactions of 43rd Annual Meeting Orthopaedic Research Society, 756, 1997.

82. SR Blair, RH Mayeux, AL Ogden, DP Mukherjee, KK Sadasivan and JA Albright: Glenohumeral Stability of the Shoulder, the Role of Labrum, Coracoid and Acromion. Transactions of 43rd Annual Meeting Orthopaedic Research Society, 882, 1997.

83. J.M Wittenberg, DP Mukherjee, BR Smith, and RN Kruse: Biomechanical Examination of New Fixation Devices for Mandibular Angle Fractures. Int. J. Oral Maxillofac. Surg., 26:68-73, 1997.

84. CD Clark, RH Mayeux, M Palmer, DP Mukherjee, KK Sadasivan, JA Albright: A Biomechanical Evaluation of a Posterior Glenohumeral Lesion. Orthopaedic Transactions (AOA Residents Conference), J Bone Joint Surg., 20(4): 880, 1996-1997.

85. AL Ogden, RH Mayeux, and DP Mukherjee: Wear Properties of Ultra High Molecular Weight Polyethylene Material. Proceedings of the Sixteenth Southern Biomedical Engineering Conference, pp 84-87, April 4-6, 1997.

86. G Lynn, DP Mukherjee, RN Kruse, KK Sadasivan, and JA Albright: Mechanical Stability of Thoracolumbar Pedicle Screw Fixation: The Effect of Crosslinks. Spine, 22(14): 1568-1573, 1997.

87. JW Sikes, BR Smith, DP Mukherjee, and KA Coward: The Effect of Bony Buttressing on Fixation Strengths of Locking Head and Conventional Screws in Both a Fracture and Reconstruction Model. American College of Oral and Maxillofacial Surgeons, 18th Annual Conference, Oral Abstract presentation, Mar. 20-23, 1997.

88. DP Mukherjee, M Pearson, SH Rogers, and P. Menon.: In Vitro and In Vivo Evaluations of a New Synthetic Bone Graft Material. Material Research Society, Symposium O: Polymers in Orthopaedics, December 3-4, 1997, Boston, pp. 350.

89. JA Albright, EF Berkman, TC Mitchell, and DP Mukherjee: Plaster of Paris for Delivery of Antibiotics in Osteomyelitis Poster Presentation, 10th Combined Meeting Orthopaedic Associations of the English Speaking World, February 1-6, 1998, Auckland, New Zealand.

90. DP Mukherjee, S Ashroff, NR Dorairaj, S Rogers: Surface Morphology of the Hydroxyapatite Coated Titanium Alloy Implant Material Subjected to Fatigue in the Presence of a Periodontal Pathogen. Proceedings of the 17th Southern Biomedical Engineering Conference, 123, 1998.

91. DP Mukherjee, DF Smith, SH Rogers, and JA Albright: Cell Seeding on a Biodegradable Scaffold Material. Transactions of the Society for Biomaterials, 21:541, 1998.

92. KA Coward, BR Smith, and DP Mukherjee: Comparison of Mandibular Fracture Fixation Techniques. J of the Louisiana State Medical Society, 149(11): 427, 1997.

93. M. Pearson and DP Mukherjee: In Vivo Evaluation of Hydroxyapatite (HA)/N,O Carboxyl Methyl Chitosan (NOCC) Paste in a Rat Model. J of Louisiana State Medical Society, 149(11): 431, 1997.

94. JW Sikes Jr., BR Smith, DP Mukherjee, and KA Coward: Comparison of Fixation Strengths of Locking Head and Conventional Screws in Fracture and Reconstruction Models. J. Of Oral and Maxillofacial Surgery, 56:468-473, 1998.

95. NR Dorairaj, D Mills, RD Berg, DP Mukherjee, and JA Albright: Cyclic fatigue of hydroxyapatite coated titanium alloy dental implants after exposure to a periodontal pathogen. Orthop Trans, JBJS, 21(3): 1008, 1997-1998.

96. SR Blair, RH Mayeux, AL Ogden, DP Mukherjee, KK Sadasivan, and JA Albright: Glenohumeral stability of the shoulder: Role of labrum, coracoid and acromion. Orthop. Trans, JBJS, 21(3): 1071, 1998.

97. MR Wiedmer, DP Mukherjee, JR Green, RH Mayeux, AL Ogden, KK Sadasivan, and JA Albright: Influence of the anterior labrum on the anterior-posterior translation of the shoulder. Transactions, Orthop. Research Society 45th Annual Meeting, pp 379, 1999.

98. RP Texada, DP Mukherjee, RH Mayeux, AL Ogden, KK Sadasivan, and JA Albright: Thoracolumbar fracture fixation: A novel arrangement of crosslinks. Transactions of Orthopaedic Research Society 45th Annual Meeting, pp 992, 1999.

99. HJ Granger, JR Green, DP Mukherjee, AL Ogden, and RH Mayeux: The security of a new arthroscopic knot. American Academy of Orthopaedic Surgery, Poster #396, 1999.

100. DP Mukherjee, M Pearson, R Roberts, SH Rogers, JA Albright, and AB Chausmer: Development of an experimental protocol for animal evaluations of a composite of hydroxyapatite and a water-soluble polymer. Transaction Society for Biomaterials, 22: 350, 1999.

101. DP Mukherjee, SH Rogers, D Smith,and SW Shalaby: A comparison of chondrocyte cell growth in a biodegradable scaffold with and without mixing. Transaction Society for Biomaterials, 22: 528, April 28-May 2, 1999.

102. DP Mukherjee, AL Ogden, RH Mayeux, U.Siriwardane and H. Patel: Effect of carbon coating on the properties of gamma irradiated ultrahigh molecular weight polyethylene specimens. Eighteenth Southern Biomedical Engineering Conference, May 20-23, 1999

103. TC Mitchell, KK Sadasivan, AL Ogden, RH Mayeux, DP Mukherjee, and JA Albright: Biomechanical Study of Atlantoaxial Arthrodesis: Transarticular Screw Fixation Versus Modified Brooks Posterior Wiring. J. of Orthopaedic Trauma, 13 (7): 483-489, 1999.

104. JW Sikes Jr., BR Smith, and DP Mukherjee: An invitro study of the effect of bony buttressing on fixation strength of a fractured atrophic edentuous mandible model. J. of Oral and Maxill. Surg., 58(1): 56-61, 2000.

105. R Bhati, DP Mukherjee, KJ McCarthy, S Rogers, and DF Smith: The effect of fibronectin coating on the growth of chondrocytes into a biodegradable scaffold. Abstract 41 ST National Student Research Forum, The University of Texas Medical Branch at Galveston, April 6-8, #B-4, 48, 2000.

106. KAnjali Danese, Debi P Mukherjee, Dollie Smith, Kalia K. Sadasivan, and James A Albright: Effect of Chitosan Glutamate on osteoblasts *in vitro*. Sixth World Biomaterials Congress Transactions, Vol. II, 978, 2000.

107. Debi P.Mukherjee, Shelia H Rogers, and Olubunmi T Lampejo: The reaction of polyethylene particles to tissues- an animal study. Sixth World Biomaterials Congress Transactions, Vol. II, 1480, 2000.

108. Debi P. Mukherjee, Nanda Kumar R. Dorairaj, David K. Mills, David Graham, and Jack T. Krauser: Fatigue properties of hydroxyapatite coated dental implants after exposure to a periodontal pathogen. J. Biomedical Materials Research (Applied Biomaterials), 53 (5) 467-474, 2000

109. Albert W. Pearsall, Ray H. Mayeux, Debi P. Mukherjee, and James A Albright: The effect of isometric graft posterior cruciate ligament reconstruction on anterior tibial translation. Orthopaedics, 28(6) June, 567-570, 2000.

110. Debi P Mukherjee, Dollie Smith, Richard Roberts, Sam Tunkle, and Andrew Clavenna: Evaluation of chitosan glutamate paste to repair bone defects. Annual Fall Meeting Biomedical Engineering Society, October 12-14, 2000.

111. R. S. Bhati, D. P. Mukherjee, K. J. McCarthy, S. H. Rogers, D. F. Smith, and S. W. Shalaby: The growth of chondrocytes into a fibronectin-coated biodegradable scaffold. J. Biomed Mater Res 56: 74-82, 2001.

112. Debi P. Mukherjee, Shane Smith, Michael Hartman, Shelia Rogers, Alan L. Ogden , Ray H Mayeux, and Judy Tedenton. An in-vivo evaluation of Plaster of Paris in a critical size defect model. Transaction Society for Biomaterials, 27: 415, April 24-29, 2001.

113. Debi P. Mukherjee, A S Tunkle, R. A Roberts, A Clavenna, S. Rogers, and J. Tendenton. Evaluation of a paste of chitosan glutamate and hydroxyapatite as a synthetic bone graft material. Transaction Society for Biomaterials, 27: 285, April 24-29, 2001.

114. Lois A. Nichols, Debi P. Mukherjee, Alan L. Ogden, Ray H. Mayeux, and Karl K. Bilderback, Atlantoaxial Arthrodesis by Unilateral Transarticular Screw- A Biomechanical Study, Cervical Spine Research Society, 29 th Annual Meeting, 201, Nov. 29-Dec 1,201, 2001

115. Solomon H. Chaim, Debi P. Mukherjee, Alan L. Ogden, Raymond H. Mayeux, Kalia K. Sadasivan, and James A Albright. A biomechanical study of femoral neck fracture fixation with the VHS®Vari-Angle Hip fixation system The American Journal of Orthopaedics, vol XXXI, (1S), 22-24, 2002.

116. Daniel C. Schubert, James B. Unger, Debi P. Mukherjee, and Jack P.Perrone. Mechanical performance of knots using braided and monofilament absorbable sutures. Society of Gynecologic Surgeons, 28 th Annual Scientific meeting, March 4-6, 2002.

117. Tim Talbert, Debi Mukherjee, Raymond Mayeux, Alan Ogden, and John Green. Bioabsorbable Screw Fixation in Coracoclavicular Ligament Reconstruction. Transactions 48th Annual Meeting Orthopaedic Research Society, February 10-13, 841,2002.

118. Thomas Hansen, Debi P. Mukherjee, Raymond H. Mayeux, Alan L. Ogden, Kalia K. Sadasivan, and James A. Albright. A biomechanical study of biodegradable screw fixation of medial malleolar fracture. Polymer Preprints , ACS meeting August 20,2002.

119. Daniel C. Schubert, James B. Unger, Debi Mukherjee, and Jack F. Perrone. Mechanical performance of knots using braided and monofilament absorbable sutures. Am J. of Obstet Gynecol, 187-, 2002.

120. D. P. Mukherjee, A S Tunkle, R. A Roberts, A Clavenna, S. Rogers, and D. Smith. Evaluation of a paste of chitosan glutamate and hydroxyapatite as a synthetic bone graft material. J Biomedical Materials Research Part B: Applied Biomaterials, 67B: 603-609, 2003.

121. M. Wiedmer, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux and J. R. Green. A Biomechanical Evaluation of the Role of Labrum on Anterior/Posterior translation of Shoulders at Different Degrees of Abduction. J. of Long-Term effects of Medical Implants, 13 (4), 309-318, 2003.

122. Timothy W. Talbert, John R. Green, Debi P. Mukherjee, Alan L. Ogden , R. H. Mayeux. Bioabsorbable Screw Fixation in Coracoclvicular Ligament reconstruction. J. of Long-Term effects of Medical Implants, 13 (4), 319-323, 2003.

123. S. Cox, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux, K. K. Sadasivan, J A. Albright. Syndesmosis fixation by a bioabsorbable screw, Transaction Society for Biomaterials, 29: 602, April 30-May 3, 2003

124. E. Walker, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux, K. K. Sadasivan, J A. Albright. Femoral Neck Fracture Fixation by Cannulated Screws. Poster Presentation 50 th Annual Meeting of Orthopaedic Research Society, San Francisco, March 7-10, 2004.

125. J. Anderson, D. P. Mukherjee, A.L. Ogden, R. H. Mayeux, K. K. Sadasivan. Repair of Meniscal Tear by Sutures or Devices. Poster Presentation 50 th Annual Meeting of Orthopaedic Research Society, San Francisco, March 7-10, 2004.

126. Joseph J. Ivy[1], James B. Unger[1], Debi Mukherjee. Knot Integrity with Non-Identical and Parallel Sliding Knots. American Journal of Obstetrics and Gynecology,190, 83-86, 2004 [[1]Division of Pelvic Surgery, Department of Obstetrics and Gynecology]

127. M. U.Burney, D. P. Mukherjee , A.I. Ogden , R. E. McCall. The Effects of crosslinks on the pedicle screw fixation of scoliosis, Presented in the International Meeting on Advanced spine Techniques (IMAST), Bermuda July 1-4, 2004.

128. S. Cox , D..P. Mukherjee, A. L Ogden, R H Mayuex, , K. K Sadasivan, , J. A. Albright, W.S. Pietrzak . Distal Tibio-fibular Syndesmosis Fixation: A Cadaveric, Simulated Fracture Stabilization Study Comparing Bioabsorbable and Metallic Single Screw Fixation, J. Foot and Ankle Surgery, 44(2) ,144-151, 2005.

129. L. A. Nichols, D. P. Mukherjee, A. L. Ogden, K. K Sadasivan, J. A Albright. A Biomechanical Study of Unilateral Posterior Atlantoaxial Transarticular Screw Fixation , J. of Long-Term effects of Medical Implants, 15(1), 33-38, 2005.

130. K.J. Collins, D.P. Mukherjee , A.L. Ogden, E. Robinson, K.K. Sadasivan, J.A. A Bankart Lesion Fixation- Biodegradable POP Rivet Fixator vs. Suture Repair Poster presentation in the 51st Annual Meeting of the Orthopaedic Research Society, February 20-23, 2005, in Washington, DC.

131. M. Umar Burney, Debi P. Mukherjee, Alna L. Ogden, Errin Robinson, Richard E. McCall. A Biomechnaical study of posterior spinal instrumentation using pedicle crews with and without cross-links. J of Spinal Disorders &Techniques, 2005,18(4), 364-368 .

132. D. P. Mukherjee, D. F. Smith, S. H. Rogers, B. K. Hayes. Evaluation of A bioabsorbable PGA:TMC scaffold for growth of chondrocytes. Transactions 30th Annual Meeting Soc. for Biomaterials , Memphis , TN, April 27-30, 2005 , page 12.

133. D. P. Mukherjee, D. F. Smith, S. H. Rogers, B. K. Hayes. Growth of chondrocytes and extracellular matrix production in a bioabsorbable scaffold. Transactions 30th Annual Meeting Soc. for Biomaterials , Memphis , TN, April 27-30, 2005 , page 11.

Chapter in Book

1. DP Mukherjee and AS Hoffman: Physical and Mechanical Properties of Elastin. Biophysical Properties of the Skin, H.R. Elden (ed.) John Wiley and Sons, Incorporated, New York, 1971, pp. 219-241.
2. Debi P. Mukherjee, William S. Pietrzak Bioabsorbable Fixation: Scientific and Clinical Concepts- Submitted to Orthopedic Implants : Applications, Complications, and Management, R.W.Lindsey and Z. Gugala, Maercel Decker , Inc. Publisher, June 2, 2004.

Review

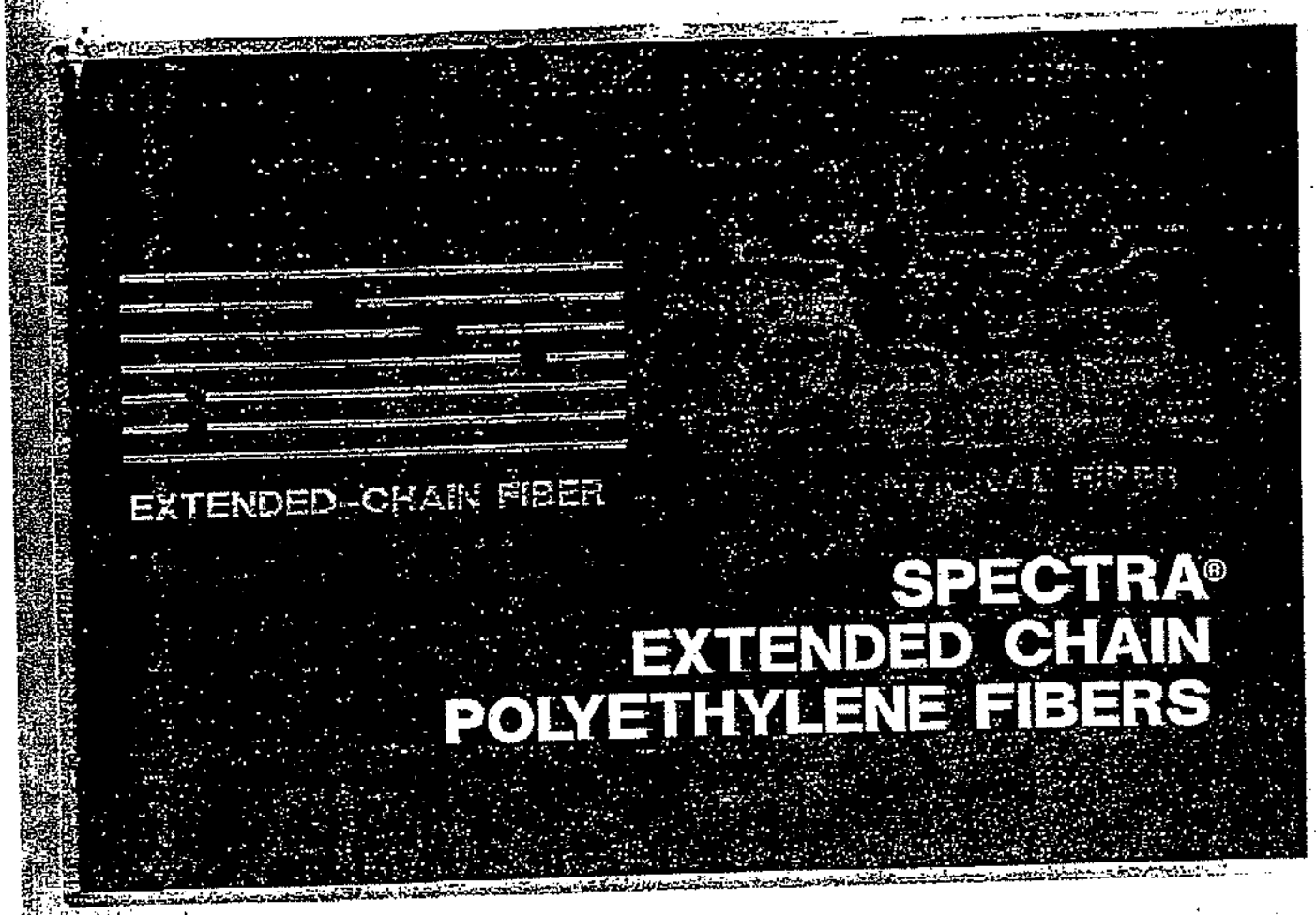
DP Mukherjee: A Review on Sutures. Encyclopedia of Polymer Science and Engineering, Vol. 16, 2nd Edition, John Wiley and Sons, pp. 473-487, (1989).

Patent

1. Debi P Mukherjee and Kurt A Feichtinger: Process for Manufacturing A Molded Prosthetic Device. U.S. Patent No. 4,808,351, February 28 1989.
2. Debi P. Mukherjee : Method for Producing Chitin or Chitosan. U.S. Patent No. 6,310,188 B1, October 30, 2001.

EXHIBIT B

15



DePuy Mitek, Inc. v. Arthrex, Inc.
C.A. No.04-12457 PBS
DMI003378

Allied Fibers

Allied Signal Technologies

SPECTRA®

HIGH PERFORMANCE FIBERS FOR REINFORCED COMPOSITES

Published by
Allied Fibers Technical Center
P.O. Box 31
Petersburg, Virginia 23804
804/520-3321

SPECTRA® EXTENDED CHAIN POLYETHYLENE FIBERS

David S. Cordova, Daniel Scott Donnelly
Allied-Signal Technologies
Fibers Division
Petersburg, VA 23804

1. HISTORY

Extended Chain Polyethylene (ECPE) fibers are the most recent entrants in the high performance fibers field. SPECTRA® ECPE, the first commercially available ECPE fiber, was introduced in February 1985. They are the first in a family of extended chain polymers manufactured by Allied-Signal Corporation.

SPECTRA® ECPE fibers are, pound for pound, the highest modulus and strongest fibers ever made. This is a noteworthy achievement on two counts. First, because industry had relegated it to the status of a general purpose commodity polymer, polyethylene was not considered as a specialized high performance product. Second, the discovery was not made in a large industrial polymer laboratory, but from fundamental work by researchers in several leading universities. Although the work was supported by industry, the immediate outcome was not foreseen as a commercial entity. It is, however, an example of industry recognizing the value of revolutionary findings and exploiting the promise of technology. The result was the transformation of a commodity type polyethylene (PE) plastic into a high performance fiber.

Today, ECPE fibers are being utilized as a reinforcement in areas that, five years ago, were not accessible to any organic fiber. Applications such as ballistic armor, impact shields, and radar domes are being developed to take advantage of the unique properties of ECPE.

2. CHEMISTRY

SPECTRA® fibers are made from ultra-high molecular weight polyethylene (UHMPE). In contrast to aramids, PE is a flexible molecule which normally crystallizes by folding back on itself. As a consequence, P.E. fibers made by conventional technology do not possess outstanding physical properties. ECPE fibers, on the other hand, are manufactured by a process where most of the molecules are fully extended and oriented in the fiber direction, resulting in a dramatic increase in physical properties. A simplistic view of the structure on a molecular scale could be described as a bundle of rods, with occasional entangled points that tie the structure together. Conventional PE, on the other hand, contains a number of chain folds of short length which do not make a contribution to strength.

The key structural parameters that distinguish ECPE fibers from conventional melt spun materials are further illustrated in Figure 1. The molecular weight of UHMPE is generally 1 to 5 million, whereas conventional P.E. fibers are typically 50,000 to several hundred thousand. SPECTRA® fibers also exhibit a very high degree of crystalline orientation (95-99%), and crystalline content (80-85%).

3. MANUFACTURING

Two general routes can be used to achieve high-modulus PE fibers. The first is by extrusion, such as melt extrusion or by solid-state extrusion, utilizing lower molecular weight PE polymer and specialized drawing techniques. These processes lead to a fiber with high modulus, but relatively low strength and high creep. The second route involves solution spinning, where very high molecular weight PE can be utilized. With this process modification, a fiber with both high modulus and high strength is produced.

The solution spinning process for a generalized extended chain fiber begins with a polymer of approximately 1-5 million molecular weight, which is dissolved in a suitable solvent. The solution serves to disentangle the polymer chains-a key step in achieving an extended chain polymer structure. The solution is fairly dilute but viscous enough to be spun using conventional melt spinning equipment. The cooling of the extrudate leads to the formation of a fiber which can be continuously dried to remove solvent or later extracted by an appropriate solvent. The fibers are generally post drawn prior to final packaging.

Unlike most high performance processes, the solution spinning process is unusually flexible, providing an almost infinite number of process and product variations. Fiber strengths from 375 KSI to 560 KSI and tensile moduli of 15 MSI to 30 MSI have been achieved on a research scale by various companies worldwide. As the solution spinning process is modified, a higher tenacity (stronger) and more thermally stable yarn is produced. Circumstantial evidence (such as increased density, heat of fusion and x-ray orientation pattern) suggests that the increased strength and stability are caused by higher degrees of molecular orientation.

4. APPLICATIONS

4.1 Fiber Properties

The comparative strengths of ECPE fibers versus other high performance fibers are summarized in Table 1. SPECTRA® 900, produced by Allied-Signal, will be used to illustrate the general properties of ECPE. SPECTRA® 1000 fibers are more stabilized, and exhibit a higher strength and modulus. In engineering terms, the tensile properties of ECPE are similar to many high performance fibers. However, because of the low density of PE (approximately 2/3 that of high modulus aramid and half that of high modulus carbon fiber), SPECTRA® fibers have extraordinarily high specific strengths and specific moduli. Pound for pound, the strength of SPECTRA® fiber is at least 35% greater than high modulus aramid or S-Glass, and about twice that of conventional high modulus carbon fiber. When comparing high performance fibers, it is often informative to employ a graphical illustration of Table 1. A two-dimensional plot of specific strength versus specific modulus for currently available fibers is given in Figure 2, again emphasizing the superior properties of SPECTRA®.

Polyethylene is also known as a system where traditional binders and wetting agents have proven to be ineffective in improving adhesion levels. ECPE fibers have shown that this characteristic is actually advantageous in specific areas. For instance, ballistic performance is inversely related to the degree of adhesion between the fiber and the resin matrix. For applications which need higher levels of adhesion and wetout, extensive research has been performed on SPECTRA® fibers. It has been found that by submitting the fiber to specific surface treatments, such as corona discharge or plasma treatments, the adhesion of the fiber to various resins is dramatically increased (see Table 2).

The main application areas being explored and commercialized today for SPECTRA® fibers are divided into two main thrusts: traditional fiber applications such as sailcloth, marine ropes, cables, sewing thread, nettings, and protective clothing; and high tech composite applications, such as ballistics, impact shields, medical implants, radomes, pressure vessels, boat hulls, sports equipment, and concrete reinforcement.

4.2 Sailcloth

World class competition of high performance sail boats (such as the Americas Cup) has become more competitive, forcing the sail industry to experiment with new materials. A winning sailcloth must possess high strength, high modulus, light weight and minimal distortion during the sailing season. Of the fiber physical properties, none are more critical than low creep and resistance to sea water and cleaning agents. Because of its superior strength-to-weight ratio and low creep response, SPECTRA® 1000 fibers are ideally suited for high performance yachting sails. Further, PE fibers are resistant to sea water and to typical cleaning solutions used in the boating industry, such as clorox (see Figure 3).

The creep behavior of SPECTRA® extended-chain fibers under typical laboratory test loadings of 3-4 gram/denier is illustrated in Figure 4. These creep levels are substantially below those encountered with conventional PE or the specialized high modulus fibers from melt spinning. At this loading, which includes the initial elastic loading component, the creep level of SPECTRA® 1000 is comparable to that of a high modulus aramid. The elastic load component is included in these results on a practical basis since it is an integral part of the sail cloth design.

4.3 Marine Ropes

High strength, light weight, low moisture absorption and excellent abrasion resistance all make ECPE a natural candidate for marine rope. Three parameters of SPECTRA® 900 rope (diameter, weight per length, and strength) are illustrated in Table 3. Since aramid fibers are the accepted standard in the high performance rope industry, aramids will be used here to provide a yardstick by which the ECPE fibers can be measured. SPECTRA® 900 braid is 12% smaller, 10% stronger and 52% lighter than the aramid product.

The important considerations in marine rope applications are load, cycling and abrasion resistance. The response of a SPECTRA® 900 rope to load cycling was measured by testing on a sheave device. The rope was repeatedly loaded to 4000 lb until it broke. In this type of test, a 12 strand ECPE braid withstood approximately eight times the number of cycles that led to failure in the control 12 strand aramid braid (Table 4). Abrasion resistance was measured by cycling the rope over an oscillating bar. In this test, 0.5 inch diameter ECPE braided rope withstood eight times the abuse of a similar aramid rope (Table 4).

4.4 Cut Resistant Gloves And Protective Clothing

The specially toughened and dimensionally stabilized SPECTRA® 1000 yarn has made a revolutionary new line of cut-resistant products. This technology offers a previously unattainable level of protection from cut and abrasion without sacrificing comfort and launderability. Spectra® fibers are being used in the form of cut resistant gloves, arm guards and chaps. Specific industries involved include: meat packing, commercial fishing, poultry processing, sheet metal work, glass cutting, and power tool use. The inert chemical nature combines with cut protection for non-permeable over-gloves in surgical, dental, laboratory testing, and police emergency response applications.

4.5 Ballistic Protection

ECPE's high strength and modulus and low specific gravity offer higher ballistic protection at a lower areal density than is possible with currently used materials. It can be used in flexible and rigid armor.

Flexible armor is manufactured by joining multiple layers of fabric into the desired shape. The style of the fabric and number of layers will determine the

ballistic resistance that the armor will provide. Typical V50 ballistic limits of plain weave SPECTRA® fabrics of different denier yarns are plotted as functions of areal density in Figure 5. Applications include protective vests for military personnel and civilian security forces as well as ballistic blankets. These blankets can be applied to ceramic and metallic armor as a front spall shield and as a rear spall suppressor. They can also be used to fabricate ballistic protective shelters.

Traditional rigid armor can also be made by utilizing woven ECPE fiber in either thermoset or thermoplastic matrices. These rigid systems exhibit high ballistic protection due to the fiber strength and modulus in combination with its low specific gravity; that is, maximum ballistic protection is achieved with minimum weight. This increased protection is illustrated in Figure 6, which compares V50 values for SPECTRA® fiber and aramid composites against a 22 caliber fragment simulator.

The ECPE fiber ballistic systems can be contoured or formed into armored plates, helicopter seats, Army or police helmets, and many other product forms. It is important for these systems to maintain their ballistic protection under a wide range of environmental conditions. For example, Figure 7 illustrates the superior performance of SPECTRA® fiber armor, even at temperatures as high as 225°F. This performance, along with the low moisture absorption, chemical inertness, and low weight characteristics make ECPE fibers a natural in the ballistic area.

4.6 Composites

ECPE fibers are recent entrants into the high performance composite industry. Their high strength and high modulus were the main attributes which attracted the composite industry, leading to the investigation of potential applications.

SPECTRA® fibers have been used with a wide variety of resin systems, including: epoxies, polyesters, vinylesters, silicones, urethanes and polyethylene. The choice of resin is most often dictated by the end use application and requirements. Epoxy and IPN resins provide the highest mechanical properties currently reported; epoxies being used most often by the composites industry, and IPNs gaining importance in RIM/RTM processes. Vinylester and urethanes, on the other hand, offer the greatest impact and ballistic properties at the expense of mechanical strength. Polyester is intermediate to the two groups, and is most often used in the radome industry for its electrical properties. ECPE fibers can be processed essentially the same as aramid, graphite, and glass. Hand layup, matched mold, pressure, and vacuum molding of fabric prepregs are most often used; however, filament winding and pultrusion are also common with continuous filament.

SPECTRA® fibers can be found in various forms; roving, fabric, continuous mat, and even chopped fiber. Composite applications where high strength (i.e. tensile, flexural, or short beam shear) are needed require special fiber treatments to enhance the fiber to matrix adhesion. Allied-Signal, Inc. has developed proprietary treatments for their SPECTRA® fibers to increase the adhesion level and composite properties.

4.6.1 Composite Applications

SPECTRA® fiber reinforced materials are being developed and used widely in ballistics, radar protective domes, aerospace, sport equipment, and industrial applications. Some of these areas utilize the fiber in hybrid form, i.e. in combination with S-2 Glass, Graphite, Aramid, and/or Quartz.

Ballistics are so far the dominant market segment. Components include helmets, helicopter seats, automotive and aircraft armor, bullet proof radomes, and other industrial structures.

Radar protective domes (radomes) is another market utilizing ECPE fibers. Because of the excellent electrical properties of polyethylene, SPECTRA® composite systems act as a shield that is virtually transparent to microwave signals, even in high frequency regions. Hybridization with quartz or glass fiber are also attractive from the structural, cost, and performance point of view.

The major sport equipment applications to date have been canoes, kayaks, snow and water skis. Numerous other sport applications are under development, including: bicycles, golf clubs, ski poles, and tennis rackets. Further growth is expected in formula race car bodies.

The industrial market is taking advantage of SPECTRA® fibers in areas where increased strength, impact resistance, non-catastrophic failure, lightweight, or corrosion resistance are required. The corrosion resistance has led the composite industry to investigate applications where parts are exposed to a wide variety of chemical elements. Until now, standard high performance fibers could not function under such adverse conditions.

5. PROPERTIES OF COMPOSITES

The various fiber characteristics discussed so far can be translated into several unique composite properties. The following discussion will be organized into the following categories:

1. Ballistic
2. Impact
3. Electrical
4. Structural

5.1 Ballistic Performance

The ballistic performance of SPECTRA® fabrics has been presented as a function of areal density and fiber denier in the ballistic protection section. The excellent protection of SPECTRA® fabrics can be translated into hard armor composites. For example, ballistic protection against .22, .30, and .50 caliber threats is summarized in Figure 8. Looking back to Figure 6, one can see the advantage of SPECTRA® composites over similar composites reinforced with aramid fibers for fragmentation protection.

Handgun projectiles present a different type of threat, and again, SPECTRA® composites face up to the challenge with reduced weight and increased protection over aramid composites. The resistance to handgun ammunition of SPECTRA® and aramid composites are compared in Table 5. In every case, the SPECTRA® composites demonstrate lower areal density and/or increased protection.

5.2 Impact Resistance

Energy dissipation is one of the most outstanding features of ECPE. For instance, a comparison of fabric composites of SPECTRA®, Glass, Kevlar and Graphite under impact conditions is presented in Table 6. The SPECTRA® composite panels had significantly better impact properties, and were not "through penetrated" as the other panels were. Another unique behavior of SPECTRA® composites under impact loading is highlighted by repetitive impact studies. Figure 9 presents repetitive impact data for a similar SPECTRA® composite panel. Toughness gradually increases after each successive impact, working to extend the actual part life.

Drop weight instrumented impact tests were also performed on honeycomb sandwich composites. Again, the peak forces resisted by the SPECTRA® plates were consistently higher than similar aramid plates (Table 7). The peak impact force, total impact energy, and energy absorbed to peak force increase with the increase in face sheet thickness, from 1 to 3 plies. Resistance to hailstorm erosion is a practical example of the advantages that can be gained from the tremendous impact resistance offered by SPECTRA® honeycomb sandwich composites. A comparison with other reinforcements in a simulated hailstorm test is shown in Figure 10.

With the new surface treatments developed to enhance the fiber-resin interface adhesion, direct effects on the impact performance can be seen in Table 6. It should be noted that although the impact properties have decreased, the impact resistance of treated SPECTRA® composites is still five times that of glass or aramid, with a significant increase in physical properties.

5.3 Electrical Properties

Radar protective covers (radomes) are gaining an increasingly important role in today's radar systems. The most important attribute for a radome to possess is to be as close to "invisible" or "transparent" to the signal as possible. Because of the low dielectric constant and loss tangent of polyethylene, (see Table 8) SPECTRA® fiber composite systems can fulfill this requirement better than any other high performance fiber. The SPECTRA® composite low dielectric constant (2.3-2.5) has been shown to hold in the high frequency ranges, even up to the millimetric band. The superior electrical properties of ECPE fibers can be utilized in single fiber systems, or can be used to improve the properties of glass radomes via hybridization. A dielectric constant of 2.9 has been obtained with a SPECTRA®/Glass (25/75) hybrid system.

The advantages of low dielectric and low loss UHSPE fibers in radar systems can be demonstrated by observing the effect of the radome on the transmission ratio. The transmitted signal of a typical SPECTRA® radome matrix is compared with a glass radome at various ratios of wall thickness to wavelength in Figure 11. The SPECTRA® radome causes much less distortion of the signal. This advantage is even more pronounced in Type A honeycomb sandwich panels (Figure 12). By causing less signal reflection and absorbence, SPECTRA® fiber composite systems are uniquely suited to radome applications.

Other possible electrical applications for ECPE fibers and their reinforced composites are electrical shelters, x-ray tables, optical cables, and other structures where high strength non-conductive characteristics are needed.

5.4 Structural Properties

Static test results for SPECTRA® 900 and SPECTRA® 1000 unidirectional composites are summarized in Table 9. All test samples were cut from unidirectional prepregs of corona treated ECPE fiber with Shell Epon 825 epoxy resin and Mellamine 5260 cycloaliphatic diamine curing agent. The strength and modulus of SPECTRA® 1000 are higher than the SPECTRA® 900 composites, due to the improved strength of the SPECTRA® 1000 fiber. Further improvements in composite properties can be achieved by applying the plasma surface treatment to the fibers. This treatment increases the interfacial bonding, which translates into even higher composite structural properties, as described previously in Table 2.

The continuing research in improving the ECPE fiber-matrix compatibility along with hybridization with other high performance fibers open a wide new area in composite properties. These developments are currently being explored by scientists at Allied-Signal.

Figure 1. *Fiber Morphology.*

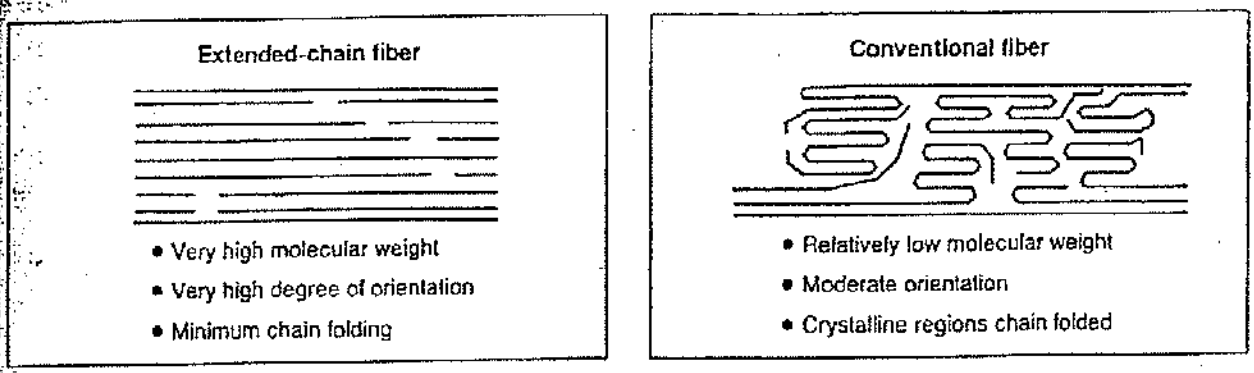


TABLE 1
HIGH PERFORMANCE FIBER PROPERTIES

Property	UHSPE SPECTRA 1000	ARAMID HM	ARAMID UHM*	S-Glass	Graphite HM
Density	0.97	1.44	1.47	2.49	1.86
Elongation, %	2.7	2.5	1.5	5.4	0.6
Tensile Strength, 10^3 psi	435	400	500	665	375
Specific Strength, 10^6 in	12.4	7.8	9.5	7.4	5.4
Tensile Modulus, 10^6 psi	25	19	25	13	57
Specific Modulus, 10^6 in	714	365	480	140	850

* Kevlar 149—Epoxy Impregnated Strand

Figure 2. *Comparative tensile properties of various reinforcing fibers.*

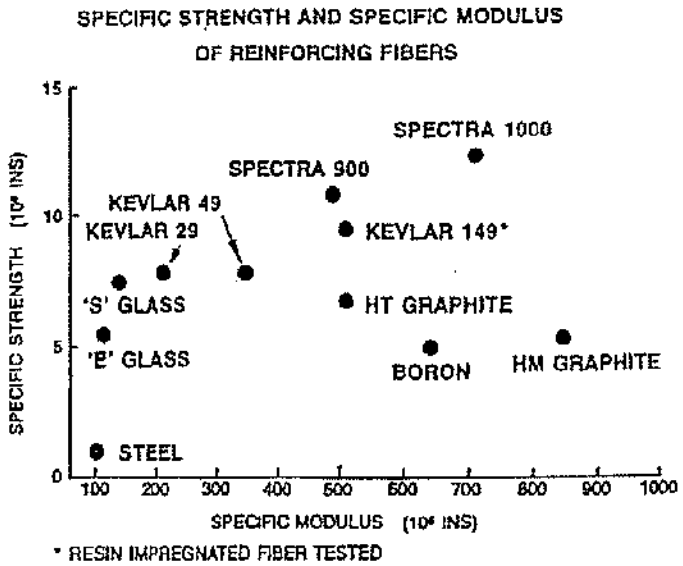


TABLE 2
UHSPE FIBER ADHESION IMPROVEMENTS

Fiber: SPECTRA® 900

Resin: Epoxy

Fiber Loading: 60%

Date	Treatment	Unidirectional SBS (KSI)	Unidirectional Flex Str (KSI)	Unidirectional Flex Mod (MSI)	Fabric (Style 903) SBS (KSI)	Fabric (Style 903) Flex Str (KSI)	Fabric (Style 903) Flex Mod (MSI)
10/85*	TN[1]	1.16	21.2	1.2	0.87	5.7	0.44
10/86	CT[2]	2.61	27.6	2.6	1.4	10.3	1.0
10/87	TP[3]	4.50	33.9	4.5	2.2	21.0	2.9

* Market Introduction [1] No Treatment [2] Corona Treatment [3] Plasma Treatment

Figure 3. *Chemical resistance.*

Agent	% Strength Retention After 6 Months Immersion SPECTRA 900	Aramid
Sea Water	100	100
10% Detergent solution	100	100
Hydraulic fluid	100	100
Kerosene	100	100
Gasoline	100	93
Toluene	100	72
Perchlorethylene	100	75
Glacial acetic acid	100	82
1M Hydrochloric acid	100	40
5M Sodium hydroxide	100	42
Ammonium hydroxide (29%)	100	70
Hypophosphite solution (10%)	100	79
Clorox®	91	0

Immersed in various chemical substances for a period of 6 months. SPECTRA fibers retained their original strength.

Figure 4. *Creep at 10% load (room temperature).*

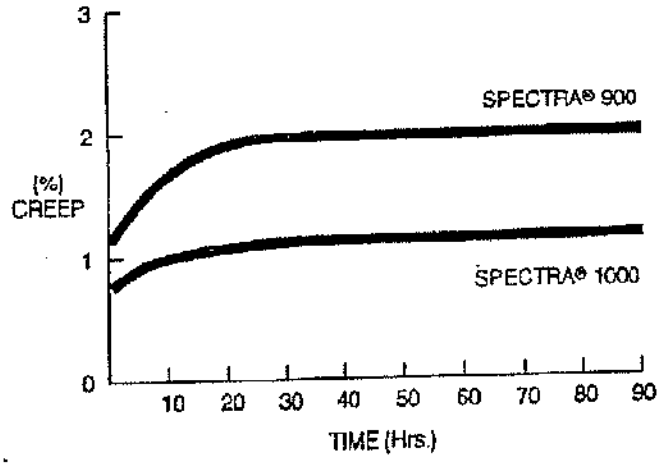


TABLE 3
COMPARATIVE PROPERTIES OF 16-STRAND ROPE

Property	SPECTRA® 900	Aramid
Diameter (In)	0.088	0.10
Wt/100 Ft (Lb)	0.153	0.32
Tensile Strength (Lb)	1465	1334

TABLE 4
CYCLE LOADING AND WEAR TESTS

	SPECTRA® 900	Aramid
Cyclic Sheave – 12 Strand Braid (10 Cycles/Min, 4000 Lb Tensile Load) Cycles to Break	10,231	1212
Oscillating Bar – 0.5 In. Rope (1.5 Cycles/Min, 1700 Lb Tensile Load) Cycles to Break	883	111

Figure 5. *Ballistic performance of SPECTRA® fabrics.*

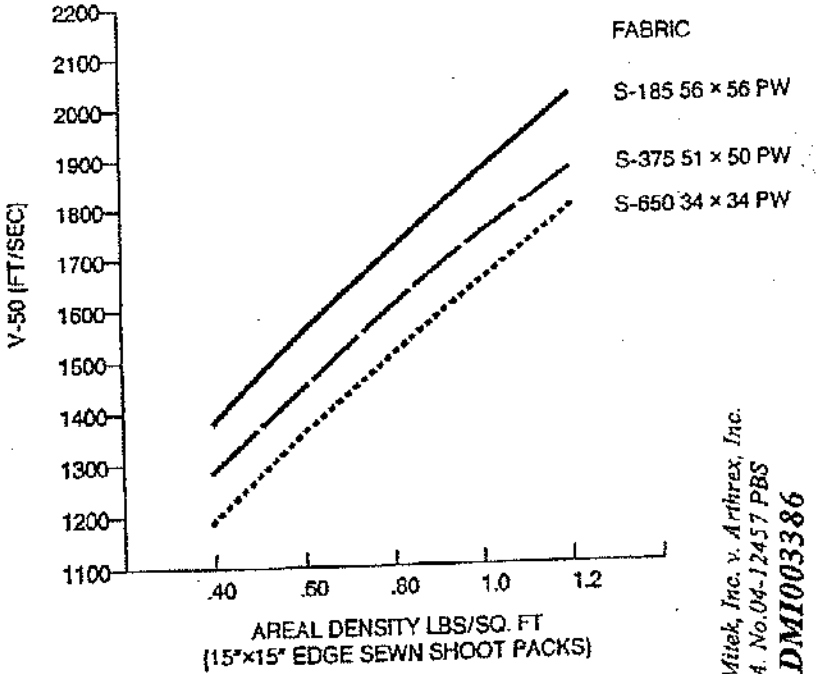


Figure 6. *Ballistic performance of Spectra® and Aramid composites.*

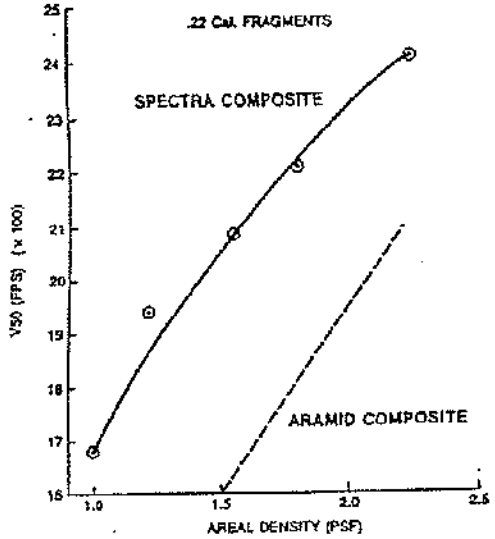


Figure 7. *Spectra® fabric ballistic performance at elevated temperatures.*

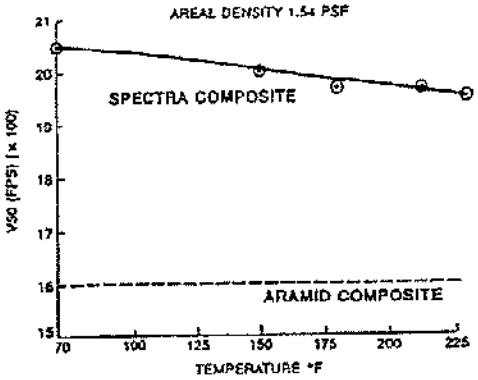


Figure 8. *Spectra® composite ballistic protection versus .22, .30 & .50 caliber fragments.*

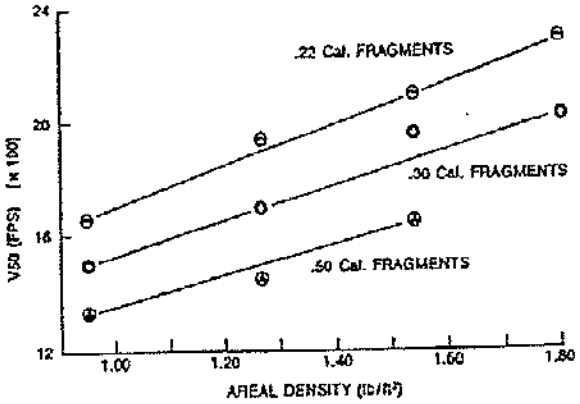


TABLE 5
RESISTANCE TO HANDGUN AMMUNITION OF SPECTRA® AND ARAMID COMPOSITES

Ammunition	No.	Armor System	AD (PSF)	V50 (FPS)
.357 Cal. 158 grain JSP	1	Spectra/Vinylester 411-45	0.62	1220
	2	Spectra/Vinylester 411-45	1.12	1443
	3	Kevlar/Polyester	1.15	1281
	4	Spectra/Vinylester 411-45	1.36	1481
	5	Kevlar/Polyester	1.49	1311
9mm 124 grain FMJ	6	Spectra/Vinylester 411-45	0.62	1082
	7	Spectra/Latex	0.70	1200
	8	Spectra/Vinylester 411-45	0.83	1173
	9	Spectra/Latex	1.01	1454
	10	Spectra/Latex	1.23	1594
	11	Kevlar/Polyester	1.28	1241
	12	Kevlar/Polyester	1.46	1372
	13	Spectra/Latex	1.53	1624

Products: Spectra 1000 and Kevlar 29

TABLE 6
INSTRUMENTED IMPACT OF FABRIC COMPOSITES

Resin: Epoxy Resin

Fiber Vol. Loading: 60%

Fiber	Treatment	Max Load (Lb)	Energy At Max Load (Ft-Lb)	Total Energy (Ft-Lb)	Observation
SPECTRA 900	TN[1]	1660	47.4	54.5	No Penetration
SPECTRA 900	TP[2]	1030	12.0	28.0	Penetration
Kevlar 49	EC[3]	254	1.3	6.7	Penetration
S-2 Glass	EC	370	1.8	4.4	Penetration
HM Graphite	EC	133	1.2	2.5	Penetration

[1] No Treatment [2] Plasma Treatment [3] Epoxy Compatible

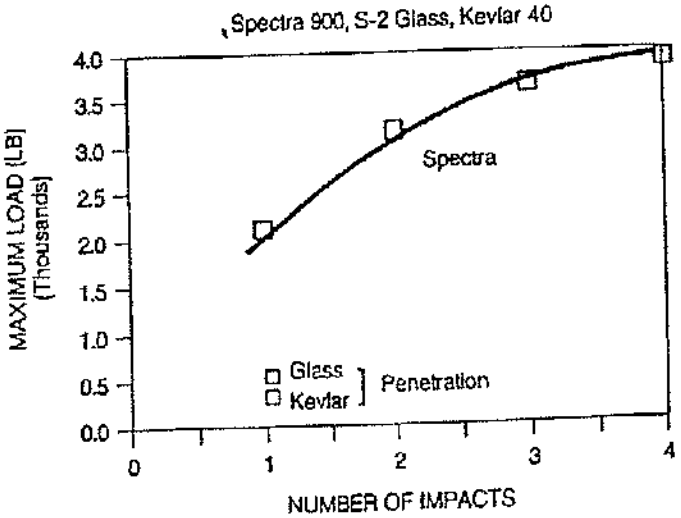


Figure 9. *Repetative impact of Spectra® composites.*

TABLE 7
IMPACT ABSORPTION OF SANDWICH COMPOSITES

Core: ½ in. honeycomb (3 lb./cu. ft.)
Resin: Epoxy (Epon 826)

Skin	No. of Layers	Energy to Peak Force (ft. lb.)	Total Energy Absorbed (ft. lb.)
SPECTRA 900	1	22.4	61.5
Aramid	1	0.7	2.3
SPECTRA 900	3	33.5	59.8
Aramid	3	1.5	10.5

Figure 10. *Hailstorm test on Type A composite sandwich panels courtesy of Norton Company, Ravenna, OH.*

TABLE 8
FIBER ELECTRICAL PROPERTIES

Material	Dielectric Constant	Loss Tangent
SPECTRA	2.0-2.3	0.0002-0.0004
E-Glass	4.5-6.0	0.0060
Aramid	3.85	0.0100
Quartz	3.78	0.0001-0.0002

Figure 11. *Transmission versus relative thickness for flat panels at 8.5 GHZ.*

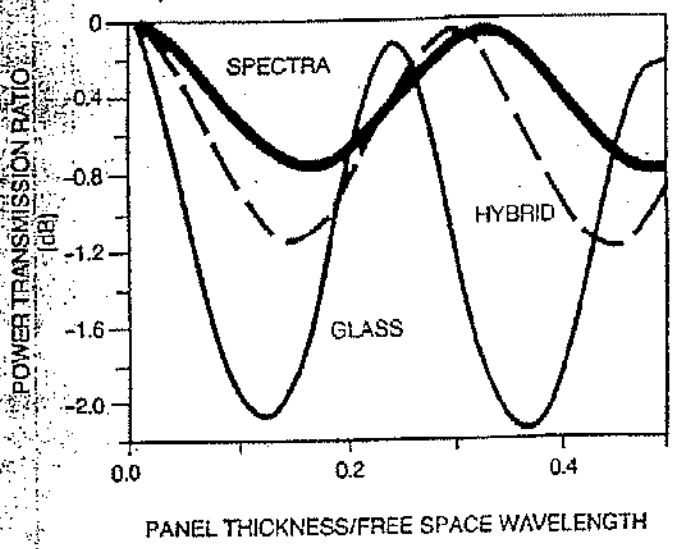


Figure 12. *Transmission versus relative thickness Type A, sandwich radome test panel at 8.5 GHZ.*

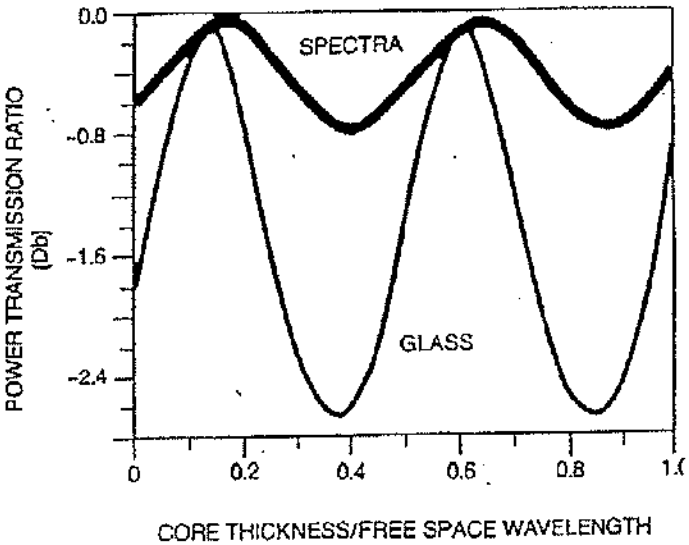


TABLE 9
PROPERTIES OF UNIDIRECTIONAL COMPOSITES (NON TREATED FIBER)

	Spectra® 900	Spectra® 1000
Axial tensile strength (10^3 psi)	174	217
Axial tensile modulus (10^6 psi)	5.8	9.1
Axial strain to failure (%)	3.8	2.6
Major Poisson's Ratio	0.32	0.28
Transverse tensile strength (10^3 psi)	1.4	1.5
Transverse tensile modulus (10^6 psi)	0.6	0.2
Axial compressive strength (10^3 psi)	15.8	16.0
Axial compressive modulus (10^6 psi)	—	3.6
Short beam shear strength (10^3 psi)	4.0	2.5

EXHIBIT C

(1)

Engineers' Guide to Composite Materials

John W. Weeton
Consultant
Formerly Chief of Composite Materials Branch at NASA

Dean M. Peters
Consultant

Karyn L. Thomas
ASM Editorial Staff

American Society for Metals
Metals Park, Ohio 44073

This book is a collective effort involving a large number of technical specialists. It brings together a wealth of information from world-wide sources to help scientists, engineers, and technicians solve current and long-range problems.

Great care is taken in the compilation and production of this book, but it should be made clear that no warranties, express or implied, are given in connection with the accuracy or completeness of this publication, and no responsibility can be taken for any claims that may arise.

Nothing contained in this book shall be construed as a grant of any right of manufacture, sale, use, or reproduction, in connection with any method, process, apparatus, product, composition, or system, whether or not covered by letters patent, copyright, or trademark, and nothing contained in this book shall be construed as a defense against any alleged infringement of letters patent, copyright, or trademark, or as a defense against any liability for such infringement.

Comments, criticisms, and suggestions are invited, and should be forwarded to the American Society for Metals, Metals Park, Ohio 44073.

Library of Congress Catalog Card Number: 86-72113
ISBN: 0-87170-226-6
SAN 204-7586

Editorial and production coordination by Carnes Publication Services, Inc.

PRINTED IN THE UNITED STATES OF AMERICA

Mechanical Properties of Aramid, Polyamide, Polyester, and Nylon Fibers

Fiber	Density Mg/m³	Density lb/in.³	Tensile strength MPa	Tensile strength ksi	Tensile modulus GPa	Tensile modulus 10^6 psi	Ultimate elongation, %
Aramid-Kevlar 29	1.44	0.052	3620	525	83	12	4.4
Aramid-Kevlar 49	1.44	0.052	3620	525	124	18	2.9
Polyamide	1.13	0.041	830	120	2.8	0.4	...
Polyester-Dacron Type 68	1.38	0.050	1120	162	4.1	0.6	14.5
Nylon-Du Pont 728*	1.13	0.041	990	143	5.5	0.8	18.3
Spectra-900	0.97	0.035	2590	375	117	17	...

*Unimpregnated twisted yarn test–ASTM D2256.

Effect of Tension-Tension Fatigue on Aramid (Kevlar 29) Fibers (Du Pont Co.)

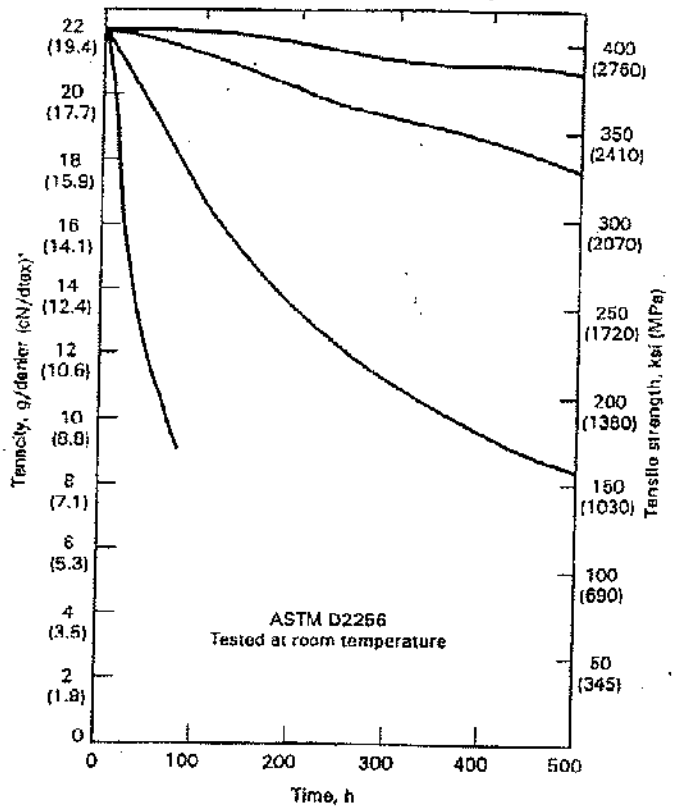
Cycled between (% of ultimate tensile strength) High	Low	No. of cycles	Break load after cycling N	Break load after cycling lb	Decrease in tensile strength due to fatigue
Control		...	552	124	...
74	45	1000	578	130	None
52	29	1000	610	137	None
31	8	1000	587	132	None
10	0	13×10^6	525	118	5%

1500 denier (1670 dtex) 2-ply yarn of Kevlar 29 was tested using air-actuated 4-D cord clamps on an Instron test machine, at 254 mm (10 in.) original gage length, 10% per minute elongation, 55% R.H., and 22 °C (72 °F).

Coating Materials Used Successfully With Kevlar 29 Aramid Fiber (Du Pont)

Coating	Typical end uses
Neoprene synthetic rubber	Inflatable boats
Hypalon synthetic rubber	Pond liners, tarpaulins
Nitrile rubber	Pressure diaphragms
Nordel hydrocarbon rubber	Heat-resistant conveyor belts
Buna-N	Hoses
Urethane polymers	Inflatable structures
Silicon and fluorosilicon	Belting
Polyvinyl chloride	Air-supported structures
Teflon (TFE, FEP) fluorocarbon resin	Nonstick belts
Polyvinyl alcohol	Specialty uses
Laminations: Tedlar polyvinyl fluoride Mylar polyester	Lighter-than-air craft

Effect of Temperature on Tensile Strength of Aramid (Kevlar 29) Fiber (Du Pont Co.)



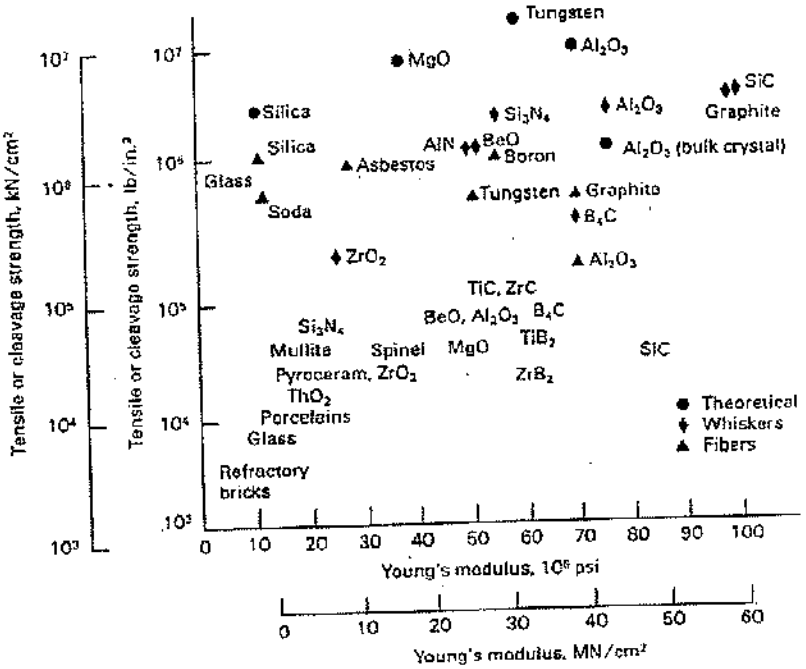
*Conversion factor: $\frac{\text{lb}}{\text{in.}^2} = \left(\frac{\text{g}}{\text{denier}}\right) \times \text{density}\left(\frac{\text{g}}{\text{cm}^3}\right) \times 12\,800$

Chemical Resistance of Kevlar (Ref 34)

Chemical	Concentration, %	Temperature °C	Temperature °F	Time, h	Strength loss, % Kevlar 29	Strength loss, % Kevlar 49
Hydrochloric acid	37	21	70	100	72	63
Hydrochloric acid	37	21	70	1000	88	81
Hydrofluoric acid	10	21	70	100	10	6
Nitric acid	1	21	70	100	16	5
Nitric acid	10	21	70	100	79	77
Sulfuric acid	10	21	70	100	9	12
Sulfuric acid	10	21	70	1000	59	31
Sodium hydroxide	10	21	70	1000	74	53
Ammonium hydroxide	28	21	70	1000	9	7
Acetone	100	21	70	1000	3	1

[continued]

Strength Vs. Modulus for Tungsten and Various Ceramics in Bulk, Fiber, and Whisker Forms (Ref 8, p 359)

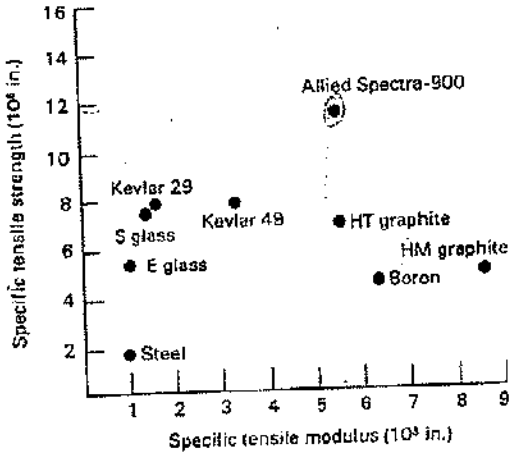


Comparative Mechanical Properties of Kevlar, Glass, and Graphite Fibers (Du Pont Co.)

Property	Kevlar 29	E glass	Graphite
Tensile strength*:			
MPa	3620	2415	2760
ksi	525	350	400
Tensile modulus*:			
GPa	82.7	68.9	220
10^6 psi	12	10	32
Density:			
g/cm³	1.44	2.52	1.74
lb/in.³	0.052	0.091	0.063
Brittleness	Tough	Brittle	Brittle
Abrasiveness	No	Yes	Yes

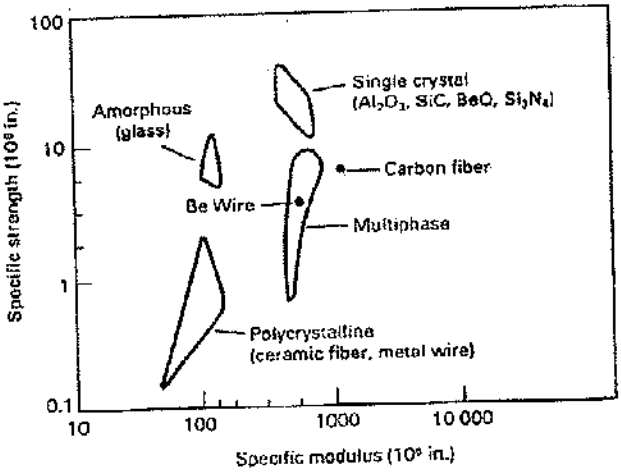
*Resin-impregnated strand test.

Specific Strength Vs. Specific Modulus for Reinforcing Fibers (Allied Fibers)



Room-Temperature Specific Strength and Specific Stiffness of Several Fibers (Ref 11, p 25)

Specific values in this figure were determined by dividing strength or modulus by density, expressed in lb/in.³ or kg/M³.



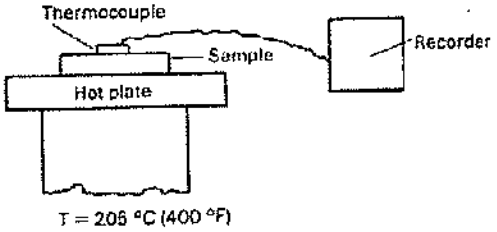
Characteristics of Carbon-Boron Alloy Fiber Groups (Ref 73)

Characteristic	Group A	Group B	Group C	Group D
Carbon interlayer	No	No	Yes	Yes
Number of CVD reaction chambers	1	3	3	3
Boron content*, wt %	43–46	35–39	46–48	48–51

*Unpublished research, D. L. McDanels, NASA Lewis Research Center.

Thermal Conductivity of Kevlar Felts and Fabrics Vs. Other Materials (Du Pont Co.)

Fabric	Weight g/m²	Weight oz/yd²	Thickness mm	Thickness mils	Lag time, s	Thermal conductivity, cal/cm²·s·°C	Temperature rise in 25 s °C	Temperature rise in 25 s °F
Kevlar 29 (1 ply)	333	9.8	0.76	30	0	0.324	60	108
Kevlar 29 (3 ply)	998	29.4	2.16	85	3	0.162	30	54
Kevlar 29 (felt)	917	27.0	2.67	105	1.5	0.084	16	28
Fiberglass (1 ply)	285	8.4	0.30	12	0	0.600	111	200
Fiberglass (8 ply)	2282	67.2	2.16	85	5.1	0.105	19	35
Asbestos	1386	40.8	2.29	90	2.5	0.168	31	55



Schematic of Test Apparatus for Determining Lag Time

Lag time is time between placing sample in contact with hot plate and any perceptible recorder readout.

Some Typical Fabric Dimensions (Hexcel-Trevarno)

Construction	Weave	Thickness, mils	Width, in.	Weight, oz/yd²
Graphite				
12.5 × 12.5	Plain	7.2	42	5.7
24.0 × 24.0	Satin	13.5	42	10.9
10.5 × 10.5	Plain	6.0	42	5.5
16.0 × 24.0	Plain	6.1	38	4.7
Kevlar				
34 × 34	Plain	4.5	38	1.8
50 × 50	Satin	11	38	5.0
22 × 22	Plain	4.5	38	2.2
17 × 17	Plain	10	38, 50	5.0
17 × 17	Crowfoot	10	38, 50	5.0
13 × 13	Plain	10	50	5.0
16 × 16	Satin	13	50	9.0
28 × 28	Basket	20	50	10.5
26 × 22	Basket	26	44, 50, 60	13.5
17 × 30	Plain	7	38	3.1
S Glass				
24 × 22	Plain	5.5	38	3.7
18 × 18	Plain	9	38	5.8
48 × 30	Crowfoot	9	38	6.8
57 × 30	Crowfoot	5.5	38	5.4
57 × 54	Satin	8.5	38	8.9
Ceramic				
48 × 47	Satin	9.0	38	7.5

Comparative Textile Fiber Properties (Ref 90)

	Spectra 900	Spectra 1000	Aramid LM	Aramid HM	Carbon HT	Carbon HM
Denier/Number of filaments	1200/118	650/120	1500/1000	1500/1000	1730/3000	1630/3000
Tenacity, g/d	30	35	22	22	20	14
Elongation, %	3.5	2.7	3.6	2.8	1.2	0.6
Tensile modulus, g/d	1400	2000	488	976	1500	2400
Shrinkage at boil, %	<1	<1				
Specific gravity	0.97	0.97	1.44	1.44	1.73	1.81
Melting point, °C	147	147				
Filament size, μm	38	27	12	12	7.0	6.5

Additives, Report NASA TN D-2757, NASA, Cleveland, Ohio, April 1965

84. C. A. Hoffman and J. W. Weeton, *Metal-Metal Laminar Composites for High Temperature Applications*, Report NASA TM X-68056, NASA, Cleveland, Ohio, May 1972

85. C. A. Hoffman and J. W. Weeton, *Tensile Behavior of Unnotched and Notched Tungsten-Copper Laminar Composites*, Report NASA TN D-8254, NASA, Cleveland, Ohio, 1976

86. E. J. Peters, and Dr. Paul Boymal, "Ceramic Fibers in Advanced Composites," Fiber Development Conference, Impact 1985, Sponsored by Marketing Technology Service, Inc., Fort Lauderdale, Florida, March 10–12, 1985

87. "Developmental Data. Fiberfrax Reinforcement of Plastics," Technical Bulletin, Sohio Engineered Materials Co., Fibers Division, Sohio Carborundum, Niagara, New York

88. J. W. Weeton and R. A. Signorelli, "Fiber-Metal Composites," *Strengthening Mechanisms-Metals and Ceramics*, edited by John J. Burke, Norman I. Reed, and Volker Weiss, Syracuse University Press, Syracuse, New York, 1966

89. John A. Alexander, Robert G. Shaver, and James C. Withers, *Critical Analysis of Accumulated Experimental Data on Filament-Reinforced Metal-Matrix Composites*, Contract No. NASW-1779, NASA, June 1969

90. "New Technology, New Horizons," Technical Bulletin, Allied Fibers Division, New York, 1985

91. Donald W. Petrasek, *High-Temperature Strength of Refractory-Metal Wires and Consideration for Composite Applications*, Report NASA TN D-6881, NASA, Cleveland, Ohio, August 1972

92. Donald W. Petrasek and Robert A. Signorelli, *Tungsten Fiber Reinforced Superalloys—A Status Review*, Report NASA TM-32590, NASA, Cleveland, Ohio, January 1981

93. *Carbon 76*, Conference proceedings of the Second International Carbon Conference, sponsored by the Working Group on Carbon of the German Ceramic Society, Baden-Baden, West Germany, 1976

94. Erich Fitzer, Antonios Gkogkidis, and Michael Heine, "Carbon Fibres and Their Composites," *High Temperatures—High Pressures*, Vol 16, 1984

95. C. T. Lynch, and J. P. Kershaw, *Metal Matrix Composites*, The Chemical Rubber Co., CRC Press, Cleveland, Ohio, 1972

96. *Plastics Engineering*, SAE, November 1985

97. *Plastics Compounding*, Harcourt Brace Jovanovich Publications, November/December 1985

98. *Material Engineering*, Penton/IPC, August 1978

99. *Modern Plastics Encyclopedia*, McGraw-Hill, 1978–1979

100. Rod Doerr, Ed Green, B. Lyon and S. Taha, *Development of Effective Machining and Tooling Techniques for Kevlar Composite Laminates*, Applied Technology Laboratories, U.S. Army Research & Technology Laboratories (AVRADCOM), June 1982

101. Anon, *A Guide to Cutting and Machining Kevlar Aramid Composites*, Du Pont Company, 1983

102. *Materials Review for '72*, SAMPE Vol. 17, Proceedings of National SAMPE Symposium and Exhibition, Los Angeles, California, April 11–13, 1972, SAMPE, Azusa, California, 1972

103. Leonard E. Samuels, *Metallographic Polishing by Mechanical Methods*, American Society for Metals, Metals Park, Ohio, 1982

104. S. R. Levitt, "High Strength Graphite Fibre/Lithium Aluminosilicate Composites," *Journal of Materials Science*, Vol 8, 1973

105. R. L. Mehan, "Effect of SiC Content and Orientation on the Properties of Si/SiC Ceramic Composites," *Journal of Materials Science*, Vol 13, 1978

106. J. Sambell, D. H. Bowen, and D. C. Phillips, "Carbon Fiber Composites with Ceramic Glass Matrices," *Journal of Materials Science*, Vol 7, 1972

107. I. W. Donald and P. W. McMillan, "Review Ceramic Matrix Composites," *Journal of Materials Science*, Vol 11, 1976

108. *Treatise on Material Science and Technology*, Vol 11, edited by R. K. MacCrone, Academic Press, Orlando, Florida, 1977

109. F. J. Jelinek, "Ceramic Composites," *Current Awareness Bulletin*, Metals and Ceramics Information Center, Columbus, Ohio, December 1985, Issue No. 154

110. *Composite Materials*, edited by L. J. Broutman and R. H. Krock, Vol. 1, *Interfaces in Metal Matrix Composites*, edited by Arthur G. Metcalfe, Academic Press, New York, 1974

111. B. I. Edelson and W. M. Baldwin, Jr., *The Effect of Second Phases on the Mechanical Properties of Alloys*, Transactions of the American Society for Metals, Volume LV, March, June, September, December, 1962, American Society for Metals, Metals Park, Ohio, 1962

112. G. E. Metzger, "Joining of Metal-Matrix Fiber-Reinforced Composite Materials," *WRC Bulletin No. 207*, Welding Research Council, 1975

113. R. L. Mehan, R. P. Jakas, and G. A. Bruch, "*Behavior Study of Sapphire Wool Aluminum Composites*," AFML-TR-68-100, May 1968, Space Sciences Laboratory, General Electric Company, Air Force Contract No. F 33615-67-C-1308

114. A. W. H. Morris and A. Burwood-Smith, "Some Properties of a Fiber-Reinforced Nickel-Base Alloy," *Fibre Science Technology*, 3(1), 1970, pp 53–78

115. R. H. Baskey, *Fiber Reinforced Metallic Composite Materials*, Clevite Corporation (AFML-TR-67-196 AD-825364), September 1967

116. N. Nilsen and J. H. Sovik, "Fatigue of Tungsten Fiber Reinforced Nickel," *Practical Metallic Composites*, Proceedings of the Spring Meeting, Institution of Metallurgists, London, 1974, pp B51–B54

117. Diane M. Essock, "FeCrAlY Matrix Composites for Gas Turbine Applications," *Advanced Fibers and Composites for Elevated Temperatures*, edited by I. Ahmad and B. R. Noton, Proceedings of the 108th AIME Annual Meeting and Symposium, sponsored by the Metallurgical Society of AIME and ASM Joint Composite Materials Committee, New Orleans, Louisiana, February 20–21, 1979, The Society of AIME, Warrendale, Pennsylvania, 1980

118. R. W. Jech and R. A. Signorelli, *Evaluation of Silicon Carbide Fiber/Titanium Composites*, TM-79232, NASA Lewis Research Center, Cleveland, Ohio, July 1979

119. I. J. Toth, W. D. Brentnall, and G. D. Menke, "Making a Product from Composites," *Journal of Metals*, Vol. 24, October 1972, Metallurgical Society/AIME

120. D. Cratchley, "Factors Affecting the UTS of a Metal/Metal-Fibre Reinforced System," *Powder Metallurgy*, No. 11, 1963

121. K. M. Prewo and K. G. Kreider, "High-Strength Boron and Borsic Fiber Reinforced Aluminum Composites," *Journal of Composite Materials*, July 1972

122. G. V. Samsonov, A. D. Panasyk and H. S. Borivikova, "Wettability and Surface Properties of Melts and Solid Bodies," Naukova Dumka, Kiev, 1972

123. V. I. Tumanov, A. E. Goyburov and G. M. Kondratenko, ibid.

124. J. Theberge et al., 30th Annual Conference, Reinforced Plastics/Composites Institute, SPI, 1972; Section 14-C

125. K. M. Prewo, "New Dimensionally and Thermally Stable Composite," Conference on Advanced Composites, Technology Conference Associates, El Segundo, CA, December 1979, p. 1

EXHIBIT D

(2)

The UHMWPE Handbook

Ultra-High Molecular Weight Polyethylene in Total Joint Replacement

Steven M. Kurtz, Ph.D.
Principal Engineer, Exponent, Inc.
Research Associate Professor, Drexel University
3401 Market Street, Suite 300
Philadelphia, PA 19104

ELSEVIER
ACADEMIC
PRESS

AMSTERDAM • BOSTON • HEIDELBERG • LONDON
NEW YORK • OXFORD • PARIS • SAN DIEGO
SAN FRANCISCO • SINGAPORE • SYDNEY • TOKYO

Contributors

Jörgen Bergström Ph.D.
Senior Engineer
Exponent, Inc.
21 Strathmore Rd.
Natick, MA 01760

Pierangiola Bracco
Researcher
Dipartimento di Chimica IFM
Università di Torino
Via Giuria 7
10125 Torino (Italy)

Luigi Costa Ph.D.
Professor
Dipartimento di Chimica IFM
Università di Torino
Via Giuria 7
10125 Torino (Italy)

Peter Cripton Ph.D.
Assistant Professor
Department of Mechanical Engineering
University of British Columbia
2054-2324 Main Mall
Vancouver, B.C.
V6T1Z4 Canada

Avram Allan Edidin Ph.D.
Research Associate Professor
School of Biomedical Engineering, Science, and Health Systems
Drexel University
3141 Chestnut St.
Philadelphia, PA 19104

Stefan Gabriel Ph.D., P.E.
Principal Engineer
Smith & Nephew Endoscopy
130 Forbes Blvd.
Mansfield, MA 02048

Stephen Spiegelberg Ph.D.
President
Cambridge Polymer Group, Inc.
52-R Roland St.
Boston, MA 02129

Marta Villarraga Ph.D.
Managing Engineer, Exponent, Inc.
Research Associate Professor
School of Biomedical Engineering, Science, and Health Systems
Drexel University
3401 Market St., Suite 300
Philadelphia, PA 19104

the elemental building blocks are individual metal atoms (e.g., Co, Cr, Mo) or relatively small molecules (e.g., metal carbides or oxides). However, in a polymer, the molecular size can comprise more than a 100,000 monomer units, with molecular weights of up to millions of g/mol.

The molecular chain architecture of a polymer also imparts many unique attributes, including temperature dependence and rate dependence. Some of these unique properties are further illustrated in the specific case of UHMWPE in subsequent sections of this chapter. For further background on general polymer concepts, the reader is referred to textbooks by Rodriguez (1989) and Young (1983).

What Is Polyethylene?

Polyethylene is a polymer formed from ethylene (C_2H_4), which is a gas having a molecular weight of 28. The generic chemical formula for polyethylene is $-(C_2H_4)_n-$, where n is the degree of polymerization. A schematic of the chemical structures for ethylene and polyethylene is shown in Figure 1.4.

For UHMWPE, the molecular chain can consist of as many as 200,000 ethylene repeat units. Put another way, the molecular chain of UHMWPE contains up to 400,000 carbon atoms.

There are several kinds of polyethylene (LDPE, LLDPE, HDPE, UHMWPE), which are synthesized with different molecular weights and chain architectures. LDPE and LLDPE refer to low-density polyethylene and linear low-density polyethylene, respectively. These polyethylenes generally have branched and linear chain architectures, respectively, each with a molecular weight of typically less than 50,000 g/mol.

HDPE is a linear polymer with a molecular weight of up to 200,000 g/mol. UHMWPE, in comparison, has a viscosity average molecular weight of up to 6 million g/mol. In fact, the molecular weight is so ultra-high that it cannot be measured directly by conventional means and must instead be inferred by its intrinsic viscosity (IV).

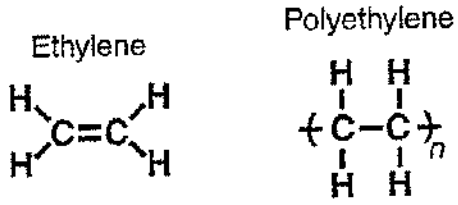


Figure 1.4
Schematic of the chemical structures of ethylene and polyethylene.

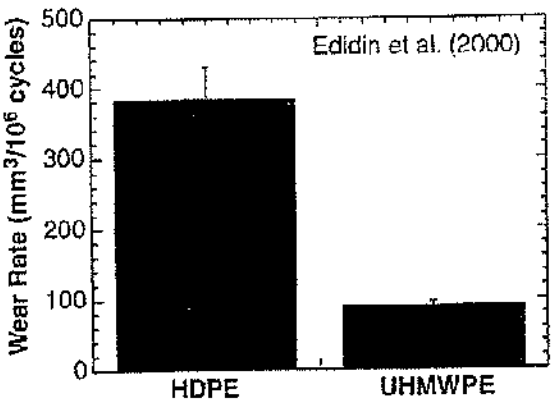


Figure 1.5
Comparison of wear rates of HDPE and UHMWPE in a multidirectional hip simulator. (From Edidin A.A., and S.M. Kurtz. 2000. The influence of mechanical behavior on the wear of four clinically relevant polymeric biomaterials in a hip simulator. *J Arthroplasty* 15:321–331.)

Crystallinity

One can visualize the molecular chain of UHMWPE as a tangled string of spaghetti, more than a kilometer long. Because the chain is not static, but imbued with internal (thermal) energy, the molecular chain can become mobile at elevated temperatures. When cooled below the melt temperature, the molecular chain of polyethylene has the tendency to rotate about the C–C bonds and create chain folds. This chain folding, in turn, enables the molecule to form local ordered, sheetlike regions known as crystalline lamellae. These lamellae are embedded within amorphous (disordered) regions and may communicate with surrounding lamellae by tie molecules. All of these morphological features of UHMWPE are shown schematically in Figure 1.6.

The degree and orientation of crystalline regions within a polyethylene depends on a variety of factors, including its molecular weight, processing conditions, and environmental conditions (such as loading), and will be discussed in later chapters.

The crystalline lamellae are microscopic and invisible to the naked eye. The lamellae diffract visible light, giving UHMWPE a white, opaque appearance at room temperature. At temperatures above the melt temperature of the lamellae, approximately 137°C, UHMWPE becomes translucent. The lamellae are on the order of 10–50 nm in thickness and 10–50 μm in length (Kurtz et al. 1999). The average spacing between lamellae is on the order of 50 nm (Bellare, Schnablegger, and Cohen 1995).

The crystalline morphology of UHMWPE can be visualized using transmission electron microscopy (TEM), which can magnify the polymer by up to

summarizes the clinical performance of UHMWPE hip implants and discusses the patterns of wear and surface damage that occur during implantation. Chapter 6 describes alternatives to conventional UHMWPE in hip replacement. Chapters 7 and 8 relate to the development and clinical performance of UHMWPE in knee replacement. Chapter 9 is devoted to clinical applications of UHMWPE in the shoulder, and Chapter 10 covers the use of UHMWPE in the spine.

The topics outlined in this *Handbook* may be used as a resource in undergraduate, as well as graduate, courses in biomaterials and orthopedic biomechanics. Students in these disciplines can learn a great deal from exposure to the historical development of total joint replacements within the context of UHMWPE. The first two main sections of this book, which cover the fundamentals of UHMWPE and clinical applications in the spine and upper and lower extremities, are intended as a resource for undergraduate instruction.

The third section of this book, which covers more specialized topics related to UHMWPE, is intended for an audience of graduate students and orthopedic researchers. Chapter 11 covers the chemistry of UHMWPE following irradiation, which leads to oxidation and crosslinking of the material. Chapter 12 describes the characterization methods for UHMWPE in the context of regulatory submissions prior to clinical trials. In Chapter 13, we review the development of the small punch test, a miniature specimen mechanical testing technique that has recently been standardized. Chapter 14 describes the micromechanical modeling of conventional and highly crosslinked UHMWPE. The final chapter in this work, Chapter 15, is a compendium of the processing, packaging, and sterilization information for highly crosslinked and thermally treated UHMWPE materials that are currently used in hip and knee arthroplasty.

Understanding basic chemical structure and morphology is an important starting point for appreciating the unique and outstanding properties of UHMWPE. The chapters that follow and describe the processing, as well as the sterilization, of UHMWPE will continue to build on the conceptual foundation established in this introduction.

References

Bellare A., H. Schnablegger, and R.E. Cohen. 1995. A small-angle x-ray scattering study of high-density polyethylene and ultra-high molecular weight polyethylene. *Macromolecules* 17:2325–2333.

Charnley J. 1963. Tissue reaction to the polytetrafluoroethylene. *Lancet* II:1379.

Charnley J. 1979. Low friction principle. In *Low friction arthroplasty of the hip: Theory and practice*. Berlin: Springer-Verlag.

Chubberley A.H. 1965. Ultra-high molecular weight polyethylenes. In *Modern plastics encyclopaedia*. New York: McGraw-Hill.

Edidin A.A., and S.M. Kurtz. 2000. The influence of mechanical behavior on the wear of four clinically relevant polymeric biomaterials in a hip simulator. *J Arthroplasty* 15:321–331.

Kurtz S.M., O.K. Muratoglu, M. Evans, A.A. Edidin. 1999. Advances in the processing, sterilization, and crosslinking of ultra-high molecular weight polyethylene for total joint arthroplasty. *Biomaterials* 20:1659–1688.

Rodriguez F. 1989. *Principles of polymer systems*. New York: Hemisphere.

Wroblewski B.M., P.D. Siney, D. Dowson, and S.N. Collins. 1996. Prospective clinical and joint simulator studies of a new total hip arthroplasty using alumina ceramic heads and cross-linked polyethylene cups. *Journal of Bone & Joint Surgery* 78B:280–285.

Young R.J. 1983. *Introduction to polymers*. London: Chapman and Hall.

Chapter 1. Reading Comprehension Questions

1.1. Let A, B, and C be monomers. What is the molecular structure of a linear homopolymer?
- a) –A-A-B-A-A-B-A-A-B-
- b) –A-B-C-A-B-C-A-B-C-
- c) -B-C-C-C-C-C-C-C-C-
- d) –B-B-B-B-B-B-B-B-B-
- e) –C-A-A-C-A-A-C-A-A-

1.2. Which of the following polymers is NOT synthesized from ethylene?
- a) LLDPE
- b) PTFE
- c) UHMWPE
- d) HDPE
- e) LDPE

1.3. What is the major difference between HDPE from UHMWPE?
- a) Molecular weight
- b) Monomer
- c) Chemical composition
- d) Color
- e) All of the above

1.4. What are the crystals in polyethylene made up of?
- a) Folded molecular chains
- b) Calcium stearate
- c) Aluminum tetrachloride
- d) Copolymer
- e) Branched chain ends

1.5. UHMWPE exhibits which of the following transition temperatures?
- a) Glass transition
- b) Melting transition
- c) Flow transition
- d) Glass and melting transitions
- e) Glass, melting, and flow transitions

IN THE UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF MASSACHUSETTS

Exhibit 7

DEPUY MITEK, INC., a Massachusetts corporation, Plaintiff,	)	Civil Action
vs.	)	04-12457 PBS
ARTHREX, INC., a Delaware corporation, Defendant.	)	

- - - - -

The deposition of DEBI PRASAD MUKHERJEE was taken on Tuesday, June 13, 2006, commencing at 9:08 a.m., at the offices of Dickstein Shapiro Morin & Oshinsky LLP, 2101 L Street, N.W., Washington, D.C., before Susanne Bergling, Registered Merit Reporter and Notary Public.

- - - - -

134
Pearsalls?
A. No.
Q. In Exhibit 23 -- the first report, Exhibit 239, at the end, Exhibit 1, there's the documents reviewed and considered in connection with that report.
A. Yeah.
Q. Did you list all the documents reviewed and considered in connection with forming your opinions in Exhibit 239 in Exhibit 1 of Exhibit 239?
A. Yes.
Q. Okay. How about Exhibit 240, Exhibit 1, again, the documents reviewed and considered, did you list in Exhibit 1 to Exhibit 240 all the documents reviewed and considered in forming your opinions with respect to Exhibit 240?
A. Yes.
Q. Okay. And Exhibit 356, your rebuttal expert report, for Exhibit 356, did you list all the documents reviewed and considered in forming your opinions expressed in Exhibit 34 -- in Exhibit 356 in Exhibit 1 to that report?
A. Yes.
Q. Okay. Now, you have three reports, right?

135
A. Yeah.
Q. So, they list all of the -- they list and describe all of the opinions that you have in this case?
A. That's correct.
Q. Okay. Do you have any opinions that you've formed subsequent to signing these reports with respect to this case?
MR. TAMBURO: Objection, vague.
THE WITNESS: No.
BY MR. BONELLA:
Q. Okay. Have you looked at any additional materials since you signed the last report, Exhibit 356?
MR. TAMBURO: Objection, vague.
THE WITNESS: Related to this case?
BY MR. BONELLA:
Q. Yes.
A. Okay. No.
Q. Are you or have you been asked to prepare another expert report in this case?
A. No.
Q. In forming your report or your opinions, you listed the materials that you reviewed and considered. How did it come about that you

136
reviewed and considered those materials? Did you ask for all information bearing on an issue from the law firm or --
A. They supplied and I asked and I supplied some information.
Q. Okay.
A. So, that's how it worked. Mostly they supplied.
Q. Okay. Did you ask the law firm for all information bearing on an issue?
A. Yes.
Q. Okay. And you took their word that they gave you everything that was relevant to that information?
A. That's correct.
Q. Okay. The testing that Dr. Gitis did, were you present for that testing?
A. I was not present.
Q. Okay. The testing that Dr. Burks did, were you present for that testing?
A. No.
Q. I'm going to refer to the claims of the '446 patent today, when we talk about them, the ones that I think you have opined on are claims 1, 2, 8, 9 and 12. Is that right?

137
A. That's correct.
Q. Okay. So, when we talk about -- can we just, for shorthand, refer to the claims of the '446 patent, and when we refer to the claims of the '446 patent, we will be referring to claims 1, 2, 8, 9 and 12. Is that okay?
A. That's fine.
Q. Because those are the only ones you have opinions on, right?
A. Okay.
MR. BONELLA: Let's take a short break.
VIDEOGRAPHER: We are going off the record at 11:39.
(A brief recess was taken.)
VIDEOGRAPHER: We're back on the record at 11:47.
BY MR. BONELLA:
Q. In forming the opinions in your responsive report, Exhibit 240, do you recall any other communications you received from anyone that you used in forming your report?
A. Other than are listed here?
Q. Right.
A. No.
Q. Did you see any drafts of Dr. Burks' report

MOORE'S FEDERAL PRACTICE

THIRD EDITION

Exhibit 8

VOLUME 6

JAMES WM. MOORE

2006

LexisNexis

QUESTIONS ABOUT THIS PUBLICATION?

For questions about the **Editorial Content** appearing in these volumes or reprint permission, please call:

Mark Landis, J.D. ..... 1-800-424-0651 Ext. 3300
Joseph Fogel, J.D. ..... 1-800-424-0651 Ext. 3351
Outside the United States and Canada please call ..... (415) 908-3200

For assistance with replacement pages, shipments, billing or other customer service matters, please call:

Customer Services Department at ..... (800) 833-9844
Outside the United States and Canada, please call ..... (518) 487-3000
Fax number ..... (518) 487-3584

For information on other Matthew Bender publications, please call
Your account manager or ..... (800) 223-1940
Outside the United States and Canada, please call ..... (518) 487-3000

Library of Congress Card Number: 97–137086
ISBN 0-8205-1410-1

Cite as:
[Vol. #] *Moore's Federal Practice*, § [000.00] (Matthew Bender 3d ed.)
Example:
1 *Moore's Federal Practice*, § 4.02 (Matthew Bender 3d ed.)

Editorial Offices
744 Broad Street, Newark, NJ 07102 (973) 820-2000
201 Mission St., San Francisco, CA 94105-1831 (415) 908-3200
www.lexis.com

MATTHEW BENDER

(Rel.150-6/06 Pub.410)

[2]—Supplementation Duty Extends to Expert Witness Disclosures

The duty to supplement or correct disclosures extends to the testimony of an expert from whom a disclosure report is required (*see* § 26.23[2]),[15] even though Rule 26(e) generally applies to written discovery rather than deposition testimony. This duty applies to the information contained in the report as well as to the expert's deposition testimony.[16] It is not unusual for an expert to change opinions in preparation for and even during trial.[17] However, the last minute appearance of a new expert witness or the expansion of previously disclosed expert testimony often has the effect of undermining the adversary's trial preparations.[18]

A party may not use a supplemental report to disclose information that should have been disclosed in the initial expert report, thereby circumventing the requirement for a timely and complete expert witness report.[18.1]

Any additions or other changes with regard to the expert witness information must be disclosed by the time the party's pretrial disclosures are due under Rule 26(a)(3);[19] that is, at least 30 days before trial, unless otherwise directed by the court (*see* § 26.24).[20] As noted by one commentator, the pretrial disclosures

---

[15] *See* Fed. R. Civ. P. 26(a)(2)(B).

[16] *See* Fed. R. Civ. P. 26(e) advisory committee's note (1993) (reproduced verbatim at § 26App.09[2]).

[17] **Change in opinion from pretrial litigation.** *See* Newell Puerto Rico, Ltd. v. Rubbermaid Inc., 20 F.3d 15, 21, 22 (1st Cir. 1994) (testimony of expert was admissible despite contention that expert's testimony differed from opinions rendered during pretrial litigation).

[18] **Preparation of witnesses.** *See* Williams v. Monarch Mach. Tool Co., 26 F.3d 228, 231 (1st Cir. 1994) (one-week delay in trial granted so that adverse party may prepare its own expert witness for new line of questions and rebuttal).

[18.1] **Supplementation cannot be used to correct major omission in initial report.** *See* Keener v. United States, 181 F.R.D. 639, 642 (D. Mont. 1998) (court concluded that "supplemental" report was so substantially different from initial report that it fell outside any reasonable notion of correcting incomplete or inaccurate expert report, as contemplated by rule requiring supplementation).

9th Circuit — *See* Keener v. United States, 181 F.R.D. 639, 642 (D. Mont. 1998) (court concluded that "supplemental" report was so substantially different from initial report that it fell outside any reasonable notion of correcting incomplete or inaccurate expert report, as contemplated by rule requiring supplementation).

11th Circuit — *See* Reid v. Lockheed Martin Aeronautics Co., 205 F.R.D. 655, 662 (N.D. Ga. 2001) (plaintiff was not permitted to file "supplemental" expert witness reports, which substantially revised analysis in original reports and revised deposition testimony, after court-imposed deadline for expert witness reports and information).

[19] *See* Fed. R. Civ. P. 26(e)(1).

[20] Fed. R. Civ. P. 26(a)(3).

required by Rule 26(a)(3) are usually otherwise directed by the court, because they are contained in the court's pretrial order. Consequently, any supplementation of expert witness information should take place on or before the date of the pretrial order.[21]

[3]—Supplementation and Correction Is Continuing Duty

The duty to supplement and correct disclosures and responses is a continuing duty and no motion to compel further supplementation is required.[22] Supplementation should not be confused with motions to compel for incomplete discovery responses.[23] The duty to supplement responses is continuing. For example, if after answering interrogatories, additional information becomes known to the answering party, this information must be disclosed and no additional interrogatories are necessary to obtain this information.[24]

The duty to supplement does not depend on repeated requests by an adversary for updated information. The fact that a party's attorney does not know about the updated information is irrelevant; the duty exists nevertheless.[25]

The duty to amend is not limited to circumstances in which the failure to amend constitutes a knowing concealment.[26] Rather, the duty to supplement and correct

---

[21] Joseph, *Emerging Expert Issues Under the 1993 Disclosure Amendments to the Federal Rules of Civil Procedure,* 164 F.R.D. 97, 112 (1996); *see* Reid v. Lockheed Martin Aeronautics Co., 205 F.R.D. 655, 662 (N.D. Ga. 2001) (although Rule 26(e)(1) requires parties to supplement incorrect or incomplete information "at least" 30 days before trial, it "does not bestow on litigants unfettered freedom to rely on supplements produced after a court-imposed deadline")

[22] **Continuing duty.** *See* Alldread v. City of Grenada, 988 F.2d 1425, 1436 (5th Cir. 1993) (motion to compel need not precede court's imposition of sanction for failure to supplement expert interrogatory response).

[23] **Distinction between Rule 26(e) and Rule 37(a).** Alldread v. City of Grenada, 988 F.2d 1425, 1436 (5th Cir. 1993) (motion to compel required for sanctions under Fed. R. Civ. P. 37(a) for failure to produce but not under Fed. R. Civ. P. 26(e) for failure to supplement); *see also* Broadcast Music, Inc. v. Xanthas, 855 F.2d 233, 238 (5th Cir. 1988) (sanctions may be imposed under Fed. R. Civ. P. 37(b) for failure to produce documents only when court has entered order compelling discovery).

[24] **Duty to supplement interrogatory responses.** *See* Pasant v. Jackson Nat'l Life Ins. Co., 137 F.R.D. 255, 257 (N.D. Ill. 1991) (plaintiff had continuing obligation to supplement answers to interrogatories).

[25] **Repeated requests unnecessary.** *See* Arthur v. Atkinson Freight Lines Corp., 164 F.R.D. 19, 20 (S.D.N.Y. 1995) (nondisclosure of personal injury plaintiff's medical records unjustified).

[26] **Knowing concealment.** Fed. R. Civ. P. 26(e)(2). Prior to the 1993 amendments, parties were required to amend seasonably discovery responses on learning that the response was no longer true and the circumstances were such that the failure to amend the response was a knowing concealment. A prior response only had to be supplemented if the circumstances made failing to amend a "knowing concealment." *See* Fortino v. Quasar Co., 950 F.2d 389, 396 (7th Cir. 1991) (applying "knowing concealment" standard under pre-1993 law).

Exhibit 9

LEXSEE 2001 U.S. DIST. LEXIS 12211

CHARLES D. STEIN v. FOAMEX INTERNATIONAL, INC., et al.

CIVIL ACTION No. 00-2356

UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF PENNSYLVANIA

2001 U.S. Dist. LEXIS 12211

August 15, 2001, Filed

DISPOSITION: [*1] Defendants' Motion to Preclude GRANTED. Defendants' Motion to Strike GRANTED.

CASE SUMMARY:

PROCEDURAL POSTURE: Plaintiff property owner filed suit against defendant lessors alleging violations of several environmental statutes. The lessors subsequently moved for partial summary judgment. The lessors asserted that the property owner's expert filed an affidavit that clearly contradicted the opinions expressed in his expert report. The lessors therefore filed the instant motions to strike and to preclude.

OVERVIEW: The property owner contended that the lessors contaminated the property and he alleged violations under several federal environmental statutes. The property owner hired an environmental investigator who because the property owner's expert in the litigation. The lessors believed that the expert's affidavit contradicted his expert report and deposition testimony, and was filed only to allow the property owner to survive the motion for partial summary judgment. The court held that because the affidavit was filed after the date set for the serving of expert reports, the affidavit did not qualify as an original expert report. Also, the affidavit was not considered to be a supplement to the expert report where the changes were not made in accordance with Fed. R. Civ. P. 26. The court held that preclusion of the evidence was appropriate because the affidavit was filed in bad faith and the lessors were prejudiced by its late filing.

OUTCOME: The lessors' motions to preclude and to strike were granted.

LexisNexis(R) Headnotes

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN1] Fed. R. Civ. P. 26 requires that parties disclose the identity of any expert witness who may be used at trial. Fed. R. Civ. P. 26(a)(2)(A). That disclosure must also be accompanied by a written report prepared and signed by the witness. Fed. R. Civ. P. 26(a)(2)(B). The expert report shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor, as well as the data or other information considered by the witness in forming the opinions. Assuming the court establishes a schedule for such disclosures, parties must disclose their expert reports at the times and in the sequences directed by the court. Fed. R. Civ. P. 26(a)(2)(C).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN2] Fed. R. Civ. P. 26 imposes a duty to supplement expert reports.

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN3] See Fed. R. Civ. P. 26(e)(1).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN4] Any additions or changes to the information contained in an expert report shall be disclosed by the time

the parties disclosures under Fed. R. Civ. P. 26(a)(3) are due. Disclosures pursuant to Fed. R. Civ. P. 26(a)(3) shall be made, unless otherwise directed by the court, at least 30 days before trial. Fed. R. Civ. P. 26 (a)(3).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
Civil Procedure > Discovery > Misconduct
[HN5] Failure to properly disclose or supplement information in accordance with Fed. R. Civ. P. 26 can result in sanctions pursuant to Fed. R. Civ. P. 37(c)(1). Fed. R. Civ. P. 37 provides that a party that without substantial justification fails to disclose information required by Fed. R. Civ. P. 26(a) or Fed. R. Civ. P. 26(e)(1) is not, unless such failure is harmless, permitted to use as evidence at a trial any witness or information not so disclosed. Fed. R. Civ. P. 37 provides for other sanctions as well, and the determination of which sanction to impose is within the sound discretion of the trial court.

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
Civil Procedure > Discovery > Misconduct
[HN6] Discretion notwithstanding, the exclusion of critical evidence is an extreme sanction. Indeed, the United States Court of Appeals for the Third Circuit requires more than a literal violation of Fed. R. Civ. P. 26; before a court preludes a party from presenting certain evidence at trial, it must first find that the party: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence. When making those determinations, courts should consider: (1) the prejudice or surprise in fact of the party against whom the excluded evidence would have been offered; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the Fed. R. Civ. P. 37 sanctions would disrupt the orderly and efficient trial of the case or of other cases in the court; and (4) bad faith or willfulness of the party failing to make a required disclosure.

Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN7] Fed. R. Civ. P. 56 permits parties bringing a motion for summary judgment to accompany that motion with supporting affidavits. Fed. R. Civ. P. 56(a). A party defending a motion for summary judgment may also employ supporting affidavits. Fed. R. Civ. P. 56(b). Supporting affidavits are subject to several requirements.

Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN8] In a motion for summary judgment, supporting affidavits must be made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein. Fed. R. Civ. P. 56. Supporting affidavits must be brought in good faith; if a litigant offers a supporting affidavit in bad faith or solely for the purpose of delay, the court shall forthwith order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused the other party to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt.

Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN9] In a summary judgment motion, supporting affidavits may not clearly contradict prior sworn testimony. To allow parties to file supporting affidavits that contradicted prior testimony would be to allow them to subvert the purpose of motions for summary judgment. Courts may therefore disregard such affidavits. For a court to disregard and strike an affidavit, however, the contradiction must be clear; an affidavit that explains rather than contradicts prior testimony should not be disregarded. Generally, courts will only disregard an affidavit if the contradiction relates to questions actually posed to the witness. Nevertheless, courts may disregard an affidavit even if the witness was not explicitly examined on an issue, if allowing the affidavit to stand would change the flavor and theory of the case by introducing new causes of action or entirely new theories of recovery not previously disclosed.

Civil Procedure > Summary Judgment > Motions for Summary Judgment > General Overview
Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
[HN10] In the context of a summary judgment motion, even if an affidavit does conflict with prior testimony, courts should not strike it if it satisfactorily explains the contradiction in terms of a mistake made while previously testifying.

Civil Procedure > Discovery > Disclosures > General Overview
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN11] It is required that expert reports provide a complete statement of all opinions to be expressed. Fed. R. Civ. P. 26 also allows parties to supplement the opinions expressed in their experts' reports, so long as such changes are made in accordance with the rule. Fed. R. Civ. P. 26(e)(1).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN12] Fed. R. Civ. P. 26 requires that expert reports contain a complete statement of all opinions to be expressed and the data or other information considered by the witness in forming the opinions, while it only provides for the supplementation of information contained in an expert report. Fed. R. Civ. P. 26(a)(2)(B), (e)(1). When read in conjunction, these provisions might lead one to believe that the Rule allows only for the supplementation of information on which opinions are based, but not the opinions themselves. The Advisory Committee Notes state, however, that the rule's duty to supplement requires disclosure of any material changes made in the opinions of an expert from whom a report is required. Fed. R. Civ. P. 26 advisory committee's note (1993).

Civil Procedure > Discovery > Disclosures > Mandatory Disclosures
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN13] Supplementation of expert reports shall be disclosed by the time the parties disclosures under Fed. R. Civ. P. 26(a)(3) are due. Disclosures pursuant to Fed. R. Civ. P. 26(a)(3) shall be made, unless otherwise directed by the court, at least 30 days before trial. Fed. R. Civ. P. (a)(3).

Civil Procedure > Counsel > General Overview
Civil Procedure > Discovery > Disclosures > General Overview
Civil Procedure > Discovery > Methods > Expert Witness Discovery
[HN14] Fed. R. Civ. P. 26 requires that expert reports be prepared and signed by the witness. Fed. R. Civ. P. 26(a)(2)(B). Fed. R. Civ. P. 26 advisory committee's notes state that the rule does not preclude counsel from providing assistance to experts in preparing the reports. Fed. R. Civ. P. 26 advisory committee's notes (1993). Nevertheless, Fed. R. Civ. P. 26(a)(2)(B) does not contemplate blanket adoption of reports prepared by counsel or others.

Civil Procedure > Pleading & Practice > Defenses, Demurrers, & Objections > Motions to Strike > General Overview
[HN15] In order to preclude a party from presenting evidence, the Third Circuit requires that the offending party must have: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence.

Civil Procedure > Summary Judgment > Supporting Materials > Affidavits
Civil Procedure > Sanctions > General Overview
Legal Ethics > Sanctions > General Overview
[HN16] Fed. R. Civ. P. 56(g) makes the filing of an affidavit in bad faith a sanctionable act that justifies holding a party or an attorney in contempt.

COUNSEL: For CHARLES D. STEIN, PLAINTIFF: JANICE V. QUIMBY-FOX, JOHN M. ARMSTRONG, SCHNADER, HARRISON, SEGAL & LEWIS, PHILA, PA USA.

For FOAMEX INTERNATIONAL, INC., FOAMEX L.P., FOAMEX CARPET CUSHION, INC., GENERAL FELT INDUSTRIES, INC./GFI-FOAMEX, MARSHALL S. COGAN, DEFENDANTS: GAYLE G. GOWEN, PHILADELPHIA, PA USA. GLEN R. STUART, MORGAN, LEWIS & BOCKIUS, PHILADELPHIA, PA USA.

JUDGES: JAMES McGIRR KELLY, J.

OPINIONBY: JAMES McGIRR KELLY

OPINION:

MEMORANDUM AND ORDER

J. M. KELLY, J.

Presently before the Court are a Motion to Strike and a Motion to Preclude, both of which were filed by the Defendants, Foamex International, Inc., Foamex L.P., Foamex Carpet Cushion, Inc., Trace International Holdings, Inc., General Felt Industries, Inc., GFI-Foamex and Marshall S. Cogan (collectively referred to as the "Defendants"). In this case, the Plaintiff, Charles D. Stein ("Stein"), filed suit against the Defendants, alleging vio-

lations of several environmental statutes. Stein served an Expert Report in support of his claims. The Defendants subsequently filed a Motion for Partial Summary Judgment. The Defendants [*2] assert that, in order to survive the Motion for Summary Judgment, Stein's expert filed an Affidavit that clearly contradicts the opinions expressed in his Expert Report. The Defendants have therefore filed the instant Motions. For the following reasons, those Motions are granted.

I. BACKGROUND

Stein is the owner of a twenty-two acre industrial property located in Philadelphia. The Defendants or their predecessors had leased that property from Stein for forty years. As part of their operations, the Defendants installed several underground storage tanks on the property. Stein alleges that, at some time in 1996 while the Defendants were occupying his property, it became contaminated. Stein filed his Complaint against the Defendants, alleging, among other state law claims, violations of several federal environmental statutes. Stein seeks compensation for the damages allegedly caused to his property, as well as his investigative, remedial and legal fees.

Stein had originally hired Sadat Associates ("Sadat") to perform environmental investigations on his property. Sadat prepared a May 1999 Site Characterization Report, which concluded that some vinyl chloride had been released [*3] on Stein's property. By Order of this Court, Stein had to serve any expert reports in this case no later than December 1, 2000. Stein ultimately chose Gary Brown ("Brown"), not Sadat, as his expert. Stein served Brown's Expert Report in a timely manner. Stein did not supplement that Expert Report before December 1. The Defendants deposed Brown on February 28, 2001.

Brown's Expert Report identified five areas of concern on Stein's property. See Brown Expert Report at 3. Brown summarized the first area of concern as "soils and groundwater impacted by releases of petroleum from the Fuel Oil Tanks and/or Outside Parrafin Tanks." Id. Describing this area of concern, Brown's Expert Report mentions only parrafin oil releases near the Outside Parrafin Oil Tank. Id. at 2, 4, 8. The Expert Report stated that "the foregoing areas of concern constitute releases or threatened releases of hazardous substances or petroleum." Id. at 13. Brown's Expert Report also concluded that the alleged "parrafin oil free product release at this site constitutes a substantial endangerment to human health and/or the environment . . . ." Id. When read in conjunction, these different sections [*4] of Brown's Expert Report clearly opine that parrafin oil on the property constitutes a release or threatened release that was a substantial endangerment to human health or the environment.

Importantly, nowhere does the Expert Report mention vinyl chloride as an area of concern. Although Sadat's Site Characterization Report mentioned the presence of vinyl chloride, and Brown's Expert Report mentioned the Site Characterization Report as a reference, the Expert Report neither adopted those particular findings nor vouched for their reliability. Indeed, the Expert Report does not expressly refer to that particular conclusion at all. Rather, the Expert Report simply mentions that Sadat had performed work for Stein.

The Defendants filed a Motion for Partial Summary Judgment on March 14, 2001. Briefly stated, the Defendants argued that Stein's federal statutory claims must fail because he had not presented evidence of a threshold amount of proscribed contamination. Specifically, the Defendants argued that, in order to recover, Stein would have to prove that there was an imminent and substantial environmental endangerment, and that the costs of Stein's environmental investigation work were [*5] necessary to address the release or threatened release of hazardous substances. See Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), *42 U.S.C. § 9607*(a)(4)(B) (1994); Resource Conservation and Recovery Act (RCRA), *42 U.S.C. § 6972*(a)(1)(B) (1994).

The Court granted several extensions of time in this case. Finally, on March 22, 2001, pursuant to a stipulation of the parties, the Court ordered that the case would be placed in the trial pool on May 6, 2001.

Stein then filed a Brief in Opposition to the Defendants' Motion for Partial Summary Judgment on April 6, 2001. Attached to that Brief was an Affidavit of Brown. This Affidavit asserted that: (1) there has been a release or threatened release of vinyl chloride on Stein's property; (2) the release constituted "an actual and significant threat to human health and the environment"; (3) the Defendants caused the release; and (4) certain monitoring and investigative activities on Stein's property, performed by Sadat and later by Brown, were necessary to address the release and threatened release of hazardous substances. See Brown Aff. PP 7-9, 13, [*6] 24-25.

The Defendants believe that Brown's Affidavit contradicts his Expert Report and deposition testimony, and was filed for the sole purpose of allowing Stein to survive the Defendants' Motion for Partial Summary Judgment. They therefore ask the Court to strike the Affidavit and preclude Brown from testifying about opinions not originally expressed in his first Expert Report.

II. STANDARDS OF REVIEW

1. The Defendants' Motion to Preclude

[HN1] *Federal Rule of Civil Procedure 26* requires that parties disclose the identity of any expert witness who may be used at trial. *Fed. R. Civ. P. 26(a)(2)(A)*. That disclosure must also be accompanied by a "written report prepared and signed by the witness." Id. (a)(2)(B). The expert report "shall contain a complete statement of all opinions to be expressed and the basis and reasons therefor," as well as "the data or other information considered by the witness in forming the opinions . . . ." Id. Assuming the court establishes a schedule for such disclosures, parties must disclose their expert reports "at the times and in the sequences directed by the court." Id. (a)(2)(C).

[HN2] Rule 26 also imposes a duty to supplement [*7] expert reports. Id. ("The parties shall supplement these disclosures when required under subdivision (e)(1)."). Specifically, [HN3] Rule 26(e)(1) provides that:

> [a] party is under a duty to supplement at appropriate intervals its disclosures under subdivision (a) if the party learns that in some material respect the information disclosed is incomplete . . . . With respect to testimony of an expert from whom a report is required . . . the duty extends both to information contained in the report and to information provided through a deposition of the expert . . . .

Id. (e)(1). [HN4] Any additions or changes to the information contained in an expert report "shall be disclosed by the time the parties disclosures under Rule 26(a)(3) are due." Id. Disclosures pursuant to Rule 26(a)(3) shall be made, unless otherwise directed by the court, at least thirty days before trial. Id. (a)(3).

[HN5] Failure to properly disclose or supplement information in accordance with Rule 26 can result in sanctions pursuant to *Federal Rule of Civil Procedure 37(c)(1)*. See *Fed. R. Civ. P. 37(c)(1)*. Rule 37 provides that "[a] party that without substantial justification fails to disclose [*8] information required by Rule 26(a) or 26(e)(1) . . . is not, unless such failure is harmless, permitted to use as evidence at a trial . . . any witness or information not so disclosed." Id. Rule 37 provides for other sanctions as well, and the determination of which sanction to impose is within the sound discretion of the trial court. *Newman v. GHS Osteopathic, Inc., 60 F.3d 153, 156 (3d Cir. 1995)*.

[HN6] Discretion notwithstanding, "the exclusion of critical evidence is an extreme sanction." *Meyers v. Pennypack Woods Home Ownership Ass'n, 559 F.2d 894, 905 (3d Cir. 1977)*. Indeed, the United States Court of Appeals for the Third Circuit requires more than a literal violation of Rule 26; before a court preludes a party from presenting certain evidence at trial, it must first find that the party: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence. See, e.g., *In re Paoli R.R. Yard PCB Litig., 35 F.3d 717, 791-93 (3d Cir. 1994); In re TMI Litig. Cases Consol. II, 922 F. Supp. 997, 1004 (M.D. Pa. 1996)*. When [*9] making those determinations, courts should consider: (1) the prejudice or surprise in fact of the party against whom the excluded evidence would have been offered; (2) the ability of that party to cure the prejudice; (3) the extent to which waiver of the Rule 37 sanctions would disrupt the orderly and efficient trial of the case or of other cases in the court; and (4) bad faith or willfulness of the party failing to make a required disclosure. Id.; *In re Paoli, 35 F.3d at 791; Pennypack, 559 F.2d at 905*.

2. The Defendants' Motion to Strike

[HN7] *Federal Rule of Civil Procedure 56* permits parties bringing a motion for summary judgment to accompany that motion with supporting affidavits. *Fed. R. Civ. P. 56(a)*. A party defending a motion for summary judgment may also employ supporting affidavits. Id. (b). Supporting affidavits are subject to several requirements.

First, [HN8] supporting affidavits must be "made on personal knowledge, shall set forth such facts as would be admissible in evidence, and shall show affirmatively that the affiant is competent to testify to the matters stated therein." Id. (e). Second, supporting affidavits must [*10] be brought in good faith; if a litigant offers a supporting affidavit in bad faith or solely for the purpose of delay, "the court shall forthwith order the party employing them to pay to the other party the amount of the reasonable expenses which the filing of the affidavits caused the other party to incur, including reasonable attorney's fees, and any offending party or attorney may be adjudged guilty of contempt." Id. (g).

Finally, [HN9] supporting affidavits may not clearly contradict prior sworn testimony. To allow parties to file supporting affidavits that contradicted prior testimony would be to allow them to subvert the purpose of motions for summary judgment. Courts may therefore disregard such affidavits. For a court to disregard and strike an affidavit, however, the contradiction must be clear; an affidavit that explains rather than contradicts prior testimony should not be disregarded. Compare *Hackman v. Valley Fair, 932 F.2d 239, 241 (3d Cir. 1991)* (affidavit conflicted with prior testimony), and *Martin v. Merrell Dow Pharm., Inc., 851 F.2d 703, 705 (3d Cir. 1988)* (same), and *Hyde Athletic Indus. Inc. v. Continental Cas. Co., 969 F. Supp. 289, 298 (E.D. Pa. 1997)* [*11]

(same), with *Giancristoforo v. Mission Gas & Oil Prods., Inc., 776 F. Supp. 1037, 1043 (E.D. Pa. 1991)* (affidavit clarified prior testimony). Generally, courts will only disregard an affidavit if the contradiction relates to questions actually posed to the witness. See *Farrell v. Planters Lifesavers Co., 206 F.3d 271, 284 (3d Cir. 2000); Videon Chevrolet, Inc. v. General Motors Corp., 992 F.2d 482, 488 (3d Cir. 1993)*. Nevertheless, courts may disregard an affidavit even if the witness was not explicitly examined on an issue, if allowing the affidavit to stand would change the "flavor and theory" of the case by introducing new causes of action or entirely new theories of recovery not previously disclosed. See *Pellegrino v. McMillen Lumber Prods. Corp., 16 F. Supp. 2d 574, 583 (W.D. Pa. 1996)* (concluding that counsel could not reasonably be held accountable for failing to uncover information through discovery because it greatly differed from nature of case as stated in complaint). Finally, [HN10] even if an affidavit does conflict with prior testimony, courts should not strike it if it satisfactorily explains the contradiction [*12] in terms of a mistake made while previously testifying. See *Martin, 851 F.2d at 705.*

III. DISCUSSION

1. The Defendants' Motion to Preclude

1. Whether Stein Violated Rule 26

The Court must first determine whether Stein violated Rule 26, a condition precedent to the imposition of sanctions under Rule 37 that the Defendants assume and Stein apparently conceded without inquiry. It is clear that Stein timely disclosed the identity of Brown as his expert witness, and that Brown's Expert Report was timely served before the date set by the Court. Accordingly, Brown may testify at trial and may express all opinions clearly expressed in his Expert Report. n1

n1 The Court notes that the Expert Report does violate Rule 26 in that its disclosures were incomplete when made and were not, and have yet to be, formally supplemented by Stein. Specifically, expert reports should contain "a listing of any other cases in which the witness has testified as an expert at trial or by deposition within the preceding four years." *Fed. R. Civ. P. 26(a)(2)(B)*. At the hearing on these Motions, it became clear that Brown has withheld the name of at least one such case because it was purportedly "confidential." Tr. of Hr'g at 41. Even if Brown has not testified in that matter, but instead simply prepared an expert report, Stein has still violated Rule 26(e)(2) by failing to supplement Brown's answers to interrogatories on the issue of his involvement in similar environmental cases. As the Court has already remedied this failure by ordering additional discovery and directing Stein to pay the Defendants' costs associated with a related Motion to Compel, the Court will not discuss this violation further.

[*13]

Whether Brown may testify concerning opinions expressed for the first time in his Affidavit, however, is another matter. The Affidavit was filed after the date set for the serving of expert reports. The Affidavit therefore does not qualify as an original expert report that could have been served in accordance with the Court's Scheduling Order. Nor could Stein have filed the Affidavit later than that time under Rule 26(a)(2)(c), which allows later filing for reports that are offered "solely to contradict or rebut evidence on the same subject matter identified" by the Defendants. See *Fed. R. Civ. P. 26 (a)(2)(C)*. This provision would have allowed Stein to present new theories or opinions at a later date. Stein has not argued that he offered Brown's Affidavit as a rebuttal opinion. Indeed, that argument is unavailable to Stein, as it would be internally inconsistent with his only argument thus far, namely that the Affidavit does not offer new opinions, but rather clarifies opinions already contained in the Expert Report.

Because the Affidavit cannot be considered an original expert report, the question therefore becomes whether it is an effective supplement to Brown's Expert Report. [*14] Despite Rule 26's requirement that [HN11] expert reports provide a "complete statement of all opinions to be expressed," the Rule also allows parties to supplement the opinions expressed in their experts' reports, so long as such changes are made in accordance with the Rule. See *Fed. R. Civ. P. 26(e)(1)*. n2 The Court finds that Brown's Affidavit was not filed in accordance with Rule 26.

n2 Interestingly, [HN12] Rule 26 requires that expert reports contain "a complete statement of all opinions to be expressed" and "the data or other information considered by the witness in forming the opinions," while it only provides for the supplementation of "information" contained in an expert report. *Fed. R. Civ. P. 26(a)(2)(B)*, (e)(1). When read in conjunction, these provisions might lead one to believe that the Rule allows only for the supplementation of information on which opinions are based, but not the opinions themselves. The Advisory Committee Notes state, however, that the Rule's duty to supplement "requires disclosure of any material changes

made in the opinions of an expert from whom a report is required . . . ." *Fed. R. Civ. P. 26* advisory committee's note (1993); see also *Fed. R. Civ. P. 26(a)(2)(c)* (providing for supplementation of all Rule 26(a)(2) "disclosures," not just "information" as stated in Rule 26(e)(1)).

[*15]

First, [HN13] supplementation of expert reports "shall be disclosed by the time the parties disclosures under Rule 26(a)(3) are due." Id. Disclosures pursuant to Rule 26(a)(3) shall be made, unless otherwise directed by the court, at least thirty days before trial. Id. (a)(3). Given that Stein's Pretrial Memorandum was to be filed with the Court on February 12, 2001, Brown's Affidavit, which Stein filed on April 6, was not timely filed as a supplement to his Expert Report. Moreover, even if the Affidavit had been timely served, n3 Stein would be unable to afford himself of Rule 26(e)(1), as he has argued throughout these proceedings that the Affidavit does not contradict Brown's Expert Report in any material respect. See id. (e)(1) (allowing supplementation of information in expert reports that is "incomplete or incorrect").

n3 Were it not for the fact that the Court set a date for pretrial disclosures, Stein would have been permitted to supplement Brown's Expert Report until thirty days before the instant case was to be called to trial. Id. (a)(3). By Order of March 22, the case's trial pool date was postponed until May 6, 2001. Brown's Affidavit, filed on April 6, would therefore have been filed, albeit fortuitously, as on the last permissible day.

[*16]

Second, Brown's Affidavit violates Rule 26 because Brown played no apparent role in preparing it. [HN14] Rule 26 requires that expert reports be "prepared and signed by the witness . . . ." Id. (a)(2)(B). The Advisory Committee Notes to Rule 26 state that the Rule "does not preclude counsel from providing assistance to experts in preparing the reports . . . ." *Fed. R. Civ. P. 26* advisory committee's notes (1993). Nevertheless, Rule 26(a)(2)(B) "does not contemplate blanket adoption of reports prepared by counsel or others . . . ." 6 James Wm. Moore et al., Moore's Federal Practice P 26.23[4] (3d ed. 2000). In the instant case, Stein's counsel provided more than assistance in preparing Brown's Affidavit. Indeed, at the hearing on this matter, Brown conceded that Stein's counsel, not he, prepared the Affidavit. Tr. of Hr'g at 76. Brown never claimed to have played any substantial role in its preparation, other than signing it. Although Brown implicitly referred to the existence of a second draft of the Affidavit, he gave no testimony regarding the extent of his involvement in the preparation of that draft. Moreover, the Affidavit was only filed in response to the Defendants' Motion for [*17] Partial Summary Judgment, and would not have been filed otherwise. While the language of the Affidavit explicitly mirrors the language of the federal statutes implicated in this case, Brown repeatedly testified that he was unfamiliar with the applicable legal standards under those statutes. See, e.g., id. at 45. Finally, Stein, although afforded ample opportunity to do so, offered no evidence that Brown prepared the Affidavit in any meaningful way. Accordingly, the Court finds that Brown's Affidavit violates Rule 26.

2. The Appropriate Remedy Under Rule 37

The Court has discretion in selecting the appropriate sanction for violations of Rule 26. [HN15] In order to preclude a party from presenting evidence, however, the Third Circuit requires that the offending party must have: (1) revealed previously undisclosed evidence when trial was either imminent or in progress; or (2) acted in bad faith, which is more than a mere lack of diligence. See, e.g., *In re Paoli, 35 F.3d at 793; In re TMI Litig., 922 F. Supp. at 1004.* The Court finds that preclusion of this evidence is appropriate because the Affidavit was filed in bad faith and the Defendants [*18] have been prejudiced by its late filing. n4

n4 Although the Affidavit was filed after this case was placed in the trial pool, the Court had yet to rule on two still- pending Cross-Motions for Partial Summary Judgment. Accordingly, Stein did not file the Affidavit when trial was imminent.

In essence, Stein would have the Court allow him to file preliminary expert reports and then freely supplement them with information and opinions that should have been disclosed in the initial report. That result would effectively circumvent the requirement for the disclosure of a timely and complete expert report. See, e.g., *Keener v. United States, 181 F.R.D. 639, 642 (D. Mont. 1998).* The concept of preliminary expert reports is contrary to the policies underlying Rule 26. See *In re TMI Litig., 922 F. Supp. 997, 1005 n.9; Smith v. State Farm Fire & Cas. Co., 164 F.R.D. 49, 53-54 (S.D. W. Va. 1995).* Allowing preliminary expert reports as a matter of course would afford litigants [*19] an opportunity to "mold their expert reports to meet [their opponent's] legal challenges." *In re TMI Litig., 922 F. Supp. at 1005 n.10.* Such was the case here. Brown's Affidavit was only filed in response to the Defendants' Motion for Partial Summary Judgment, and was carefully tailored, by

Stein's counsel, to dovetail with the statutory requirements the Defendants claimed Stein had failed to prove.

Although given the chance to do so, Stein offered no persuasive justification for the filing of Brown's Affidavit. Moreover, as is discussed at fuller length below, the opinions expressed in the Affidavit contradict those expressed in Brown's Expert Report. Finally, instead of supplementing Brown's expert opinions formally through an amended or supplemented expert report, Stein filed the Affidavit as an attachment to Stein's opposition to the Defendants' Motion for Partial Summary Judgment. Those facts, coupled with Stein's other Rule 26 violations and his inability to meet Court-imposed deadlines, demonstrate bad faith. n5 Simply stated, the work of Brown and Stein's counsel exceeds a mere lack of diligence. Id.

n5 As noted above, Brown's Expert Report, and the attempted supplement thereto, neglected to disclose certain information because it was purportedly confidential. Tr. of Hr'g at 41. Moreover, Stein filed his Pretrial Memorandum on March 8, 2001, despite the Court's unambiguous Order that it be filed no later than February 12.

[*20]

The Court finds that precluding this evidence is the most appropriate remedy for Stein's bad faith. Importantly, this ruling will not prevent all of Stein's claims from being heard by a jury; Stein may still rely on the opinions expressed by Brown in his Expert Report and, because the Defendants have only filed a Motion for Partial Summary Judgment, several of his claims will remain intact even assuming this ruling affects Stein's statutory claims. Accordingly, the Court will preclude Stein from relying on Brown's newly disclosed opinions at trial or in support of any motions filed with this Court.

2. The Defendants' Motion to Strike

Although the issue of the Defendants' Motion to Strike has largely been rendered moot by the Court's decision that Stein filed his Affidavit in bad faith, n6 the Court further finds that the Affidavit should be stricken from the record because it contradicts Brown's Expert Report, adding so many new opinions that it changes the flavor of the case from the one presented solely by Brown's Expert Report and depositions.

n6 See [HN16] *Fed. R. Civ. P. 56(g)* (making filing of affidavit in bad faith sanctionable act that justifies holding party or attorney in contempt). The Court notes that the Defendants have not asked the Court to impose these particular sanctions.

[*21]

In his Expert Report, Brown offered, among other opinions, an expert opinion that parrafin oil on Stein's property constituted a release or threatened release that substantially endangered human health or the environment. Nowhere does Brown's Expert Report mention the existence of a release or threatened release of vinyl chloride as an area of concern. The Defendants, based on Brown's Expert Report and deposition testimony, n7 could not have been on notice that Stein planned to base their liability on the existence, or threatened existence, of vinyl chloride. By contrast, Brown's Affidavit, which was filed after the Defendants filed their Motion for Partial Summary Judgment, offers many opinions concerning the presence of vinyl chloride and its associated health risks. Specifically, Brown's Affidavit opines that: (1) there has been a release or threatened release of vinyl chloride on Stein's property; (2) the release constituted "an actual and significant threat to human health and the environment"; (3) the Defendants caused the release; and (4) certain monitoring and investigative activities on Stein's property were necessary to address the release and threatened release of hazardous [*22] substances including, ostensibly, vinyl chloride. See Brown Aff. PP 7-9, 13, 24-25. None of these opinions appeared explicitly in Brown's Expert Report. n8

n7 For example, at his deposition, Brown stated that Stein's environmental investigations had not complied with CERCLA requirements because "the National Contingency Plan in something that deals with releases. When you investigate things and there isn't anything there by definition there isn't a release or threatened release . . . . This is not a federal . . . context like that." Brown Dep. at 239.

n8 While Brown's Expert Report stated that the nature and cost of the work on Stein's property were reasonable, Brown Expert Report at 13, it did not opine that such work was necessary in response to a release or threatened release of vinyl chloride.

Of course, Brown's Expert Report does refer to Sadat's Site Characterization Report, which mentions the existence of vinyl chloride on Stein's property. But Brown's Expert Report did not refer to that particular [*23] finding by Sadat, much less adopt it or vouch for its credibility. Indeed, Sadat's Site Characterization Report is twenty-eight pages long; simply referring to the

document in its entirety could not have put the Defendants on notice that Brown intended to express that particular opinion at trial. The filing of Brown's Affidavit altered the nature of these proceedings in a way that the Defendants, based on Brown's Expert Report and deposition, could not have anticipated. While the Affidavit may not conflict with Sadat's Site Characterization Report, it certainly conflicts with Brown's Expert Report. Brown never adopted Sadat's findings, and the mere mentioning of Sadat's Site Characterization Report as a reference document does not allow Brown, at this late juncture, to materially alter his intended expert testimony at trial.

Brown's Affidavit contradicts his Expert Report and deposition, and does not explain the contradiction in terms of a mistake in Brown's reducing his Expert Report to writing. Allowing Stein to file this contradictory Affidavit would allow him to undermine the purpose of motions for summary judgment. The Court will therefore strike the Affidavit from the record [*24] in this case. See *Hackman, 932 F.2d at 241; Pellegrino, 16 F. Supp. 2d at 583.*

ORDER

AND NOW, this day of August, 2001, in consideration of the Motion In Limine To Preclude Expert Opinions Not Expressed in the November 30, 2000 Expert Report of Gary Brown, filed by the Defendants, Foamex International, Inc., Foamex L.P., Foamex Carpet Cushion, Inc., Trace International Holdings, Inc., General Felt Industries, Inc., GFI-Foamex and Marshall S. Cogan (collectively referred to as the "Defendants") (Doc. No. 29), the Response of the Plaintiff, Charles D. Stein ("Stein"), and the Reply thereto, and in consideration of the Defendants' Motion to Strike the April 4, 2001 Affidavit of Gary Brown (Doc. No. 27), the Response of Stein and the Reply of the Defendants, as well as arguments and evidence presented at a Hearing held before this Court on July 18, 2001, it is **ORDERED** that:

1. The Defendants' Motion to Preclude is **GRANTED**. Stein is precluded from presenting expert testimony regarding matters or opinions not specifically and expressly contained in Brown's Expert Report, and from relying on such matters or opinions [*25] in support or defense of any motion before this Court.

2. The Defendants' Motion to Strike is **GRANTED**. The Affidavit of Gary Brown, filed as an attachment to Stein's Brief in Opposition to the Defendants' Motion for Partial Summary Judgment, shall be stricken from the record of this case.

3. Stein and the Defendants may, no later than fifteen (15) days after the date of this Order, submit a memorandum to the Court explaining the party's position on the effects of this Order on the Cross-Motions for Partial Summary Judgment still pending before this Court.

BY THE COURT:

JAMES McGIRR KELLY, J.

Exhibit 10

LEXSEE 2006 US DIST LEXIS 28263

SAINT-GOBAIN CORPORATION, Plaintiff/Counterclaim defendant, v GEMTRON CORPORATION, Defendant/Counterclaim plaintiff.

Case No. 1:04-cv-387

UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF MICHIGAN, SOUTHERN DIVISION

2006 U.S. Dist. LEXIS 28263

May 9, 2006, Decided

SUBSEQUENT HISTORY: Motion granted by *Saint-Gobain Corp. v. Gemtron Corp., 2006 U.S. Dist. LEXIS 28268 (W.D. Mich., May 9, 2006)*

PRIOR HISTORY: *St.-Gobain Corp. v. Gemtron Corp., 2006 U.S. Dist. LEXIS 27864 (W.D. Mich., May 9, 2006)*

COUNSEL: [*1] For Saint-Gobain Corporation, plaintiff: Barry J. Herman, Arthur Irwin Neustadt, Jean-Paul Phillipe Marie Lavalleye, Michael E. McCabe, Jr., Oblon Spivak McClelland Maier & Neustadt PC, Alexandria, VA; Mark S. Pendery, Rhoades McKee, Grand Rapids, MI.

For Gemtron Corporation, defendant: Randall G. Litton, Eugene J. Rath, III, Matthew Gipson, Price Heneveld Cooper Dewitt & Litton, Grand Rapids, MI; Stanley Allen Schlitter, Mark P. Vrla, Marshall J. Schmitt, Paul David Margolis, Jenner & Block LLP, Chicago, IL.

For Facilitative Mediator, mediator: William W. Jack, Jr., Smith Haughey Rice & Roegge, PC, Grand Rapids, MI.

For Gemtron Corporation, counter-claimant: Stanley Allen Schlitter, Mark P. Vrla, Marshall J. Schmitt, Paul David Margolis, Jenner & Block LLP, Chicago, IL; Eugene J. Rath, III, Matthew Gipson, Price Heneveld Cooper Dewitt & Litton, Grand Rapids, MI.

For Saint-Gobain Corporation, counter-defendant: Arthur Irwin Neustadt, Jean-Paul Phillipe Marie Lavalleye, Oblon Spivak McClelland Maier & Neustadt PC, Alexandria, VA; Mark S. Pendery, Rhoades McKee, Grand Rapids, MI.

JUDGES: Wendell A. Miles, Senior U.S. District Judge.

OPINIONBY: Wendell A. Miles

OPINION:

ORDER ON [*2] SAINT-GOBAIN'S MOTION TO STRIKE THE APRIL 10, 2006 TAYLOR SUPPLEMENTAL EXPERT REPORT

Presently before the court is Plaintiff/Counterclaim defendant Saint-Gobain's Motion to Strike the April 10, 2006 Taylor Supplemental Expert Report (docket no. 270). Defendant/counterclaim plaintiff Gemtron has opposed the motion. For the reasons to follow, the court **GRANTS** the motion.

Discussion

Paul Taylor is Gemtron's damages expert. Saint-Gobain seeks to have Mr. Taylor's most recent "supplemental" expert report (titled "Second Supplemental Expert Report of Paul H. Taylor, April 10, 2006") excluded because the report was not provided at least 90 days before trial as required by *Fed.R.Civ.P. 26(a)(2)(C)*. Saint-Gobain also argues that Mr. Taylor's most recent report contains substantially increased figures for both lost profits and reasonable royalties and that Gemtron has not offered a justifiable excuse for submitting a new report so close to the trial date.

Fed.R.Civ.P. 26(a)(2)(C) requires expert reports to be disclosed "at least 90 days before the trial date or the date the case is to be ready for trial" "[i]n the absence of other directions from the court or stipulation [*3] by the parties[.]" *Fed.R.Civ.P. 37(c)(1)* provides that

> A party that without substantial justification fails to disclose information required by *Rule 26(a)* or *26(e)(1)*, or to amend a prior response to discovery as required by *Rule 26(e)(2)*, is not, unless such failure is

> harmless, permitted to use as evidence at a trial, at a hearing, or on a motion any witness or information not so disclosed. In addition to or in lieu of this sanction, the court, on motion and after affording an opportunity to be heard, may impose other appropriate sanctions. . . .

Gemtron does not dispute that it did not provide Mr. Taylor's most recent report at least 90 days before trial. However, Gemtron argues that there were reasons for the belated disclosure, namely that Mr. Taylor had requested more information, Saint-Gobain also wanted this documenting information, and the parties had agreed that Saint-Gobain could depose Mr. Taylor as well as present its own rebuttal expert. (Apparently, Saint-Gobain has decided not to call the rebuttal expert, Rodney Crawford, who is not listed in the final pretrial order.)

The issue could be viewed as simply one of supplementation of expert disclosures as [*4] contemplated in *Fed.R.Civ.P. 26(e)(1)*, which in turn incorporates *Rule 26(a)(3)*, which requires disclosure at least 30 days before trial unless otherwise directed by the court. However, the court is not persuaded that Mr. Taylor's most recent report falls within boundaries of supplementation provided by *Rule 26(e)(1)*. Review of Mr. Taylor's earlier report, dated December 22, 2005, indicates that he reached a specific conclusion regarding Gemtron's lost profits which did not include lost unit sales of tempered glass because he had requested additional financial information *from Gemtron* which not yet been provided by the company for reasons having nothing to do with Saint-Gobain. Therefore, if his analysis was incomplete, it was incomplete because Gemtron did not provide its own expert with enough of its own financial information and not because of a lack of information from Saint-Gobain.

In addition, regarding reasonable royalty damages, Mr. Taylor's earlier report stated that he had "concluded to rely on the RoyaltySource and Licensing Economics Review data indicating industry and guideline patent(s) median royalty rates of approximately 5.0% of sales." Mr. Taylor does not in [*5] that earlier report state in any way that his analysis of a reasonable royalty was incomplete. To allow Gemtron to seek a change in its expert's conclusions based solely on information, such as licensing agreements, pursued by Saint-Gobain would defeat the purpose of disclosure because it would permit the bolstering of a report based solely on a desire to answer the opposing party's anticipated challenges. This would effectively amount to unlimited expert opinion preparation. See *Akeva LLC v. Mizuno Corp., 212 F.R.D. 306, 310 (M.D.N.C.2002)* ("The Court cannot accept a definition of supplementation which would essentially allow for unlimited bolstering of expert opinions. *Rule 26(e)* envisions supplementation when a party's discovery disclosures happen to be defective in some way so that the disclosure was incorrect or incomplete and, therefore, misleading. . . . It does not cover failures of omission because the expert did an inadequate or incomplete preparation. . . . To construe supplementation to apply whenever a party wants to bolster or submit additional expert opinions would reek havoc in docket control and amount to unlimited expert opinion preparation"); [*6] see also *Sharpe v. United States, 230 F.R.D. 452, 462-463 (E.D. Va. 2005)* (plaintiff not permitted to supplement expert reports in order to remedy incomplete review performed by experts). The obligation to supplement does not grant a party a right to ignore court deadlines, reopen discovery, find "new facts," generate new expert reports, and then claim different damages. *DAG Ent., Inc. v. Exxon Mobil Corp., 226 F.R.D. 95, 110 (D.D.C. 2005)*.

Gemtron argues that Saint-Gobain is not prejudiced by the belated "supplementation" of Mr. Taylor's report. However, as noted above, Mr. Taylor's most recent report substantially increases his earlier damage calculations. These increased figures establish that Saint-Gobain is indeed prejudiced by the belated disclosure.

Finally, as for Gemtron's argument that the parties had an agreement regarding expert discovery, Gemtron has not shown that the parties had an agreement that Gemtron could supplement its expert report after December 22, 2005. The evidence provided by Gemtron suggesting an agreement between the parties indicates that counsel for Saint-Gobain anticipated that Mr. Taylor would be deposed "after supplemental [*7] damages reports are exchanged." However, the e-mail documenting this agreement is dated November 1, 2005, several weeks before the date of Mr. Taylor's December 22, 2005 supplemental report; the e-mail does not imply that Saint-Gobain was agreeing to yet further supplementation after December, 2005. In addition, although Gemtron has submitted the affidavit of its counsel who states that Saint-Gobain's counsel said the parties "previously had agreed that Saint-Gobain's damages expert, Rodney L. Crawford, would be allowed to submit an expert report two weeks after [Taylor] was to be deposed[,]" this does not indicate an agreement on Saint-Gobain's part that it would not oppose amendment of Mr. Taylor's report. Gemtron has therefore not shown that Saint-Gobain agreed to a waive the 90-day disclosure requirement.

Conclusion

For the foregoing reasons, the court GRANTS Saint-Gobain's motion. The April 10, 2006 Second Supplemental Expert Report of Paul Taylor is stricken and shall not be used as evidence at trial. n1

n1 By way of a footnote in its response brief, Gemtron argues that "Mr. Taylor's report *will need to be supplemented at least one more time* to account for damages arising from the new shelves [recently added to the claims of infringement]" (emphasis supplied). It is noted that Gemtron has not requested permission to supplement Mr. Taylor's report yet again, and the current ruling is by no means intended to suggest that the court would permit one or more additional amendments to the report of Gemtron's damages expert.

[*8]

So ordered this 9th day of May, 2006.

Wendell A. Miles

Senior U.S. District Judge